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The Far Forward Life Support System (FFLSS) is intended for U.S. Army use in far forward, battlefield situations. The primary patient population is young, otherwise healthy, adult soldiers. The FFLSS must provide stabilizing medical care in the far forward environment. The device must be easily operated, highly mobile, compact and rugged, and provide automated, definitive support for a minimum of one hour. This project produced a prototype FFLSS and performance data taken on a test lung.

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2 Introduction

The Far Forward Life Support System (FFLSS) is intended for U. S. Army use in far forward, battlefield situations. The primary patient population is young, otherwise healthy, adult soldiers. The FFLSS must provide stabilizing medical care in the far forward environment. The device must be easily operated, highly mobile, compact and rugged, and provide automated, definitive support for a minimum of one hour. This project produced a prototype FFLSS and performance data taken on a test lung. The Statement of Work incorporated by reference into this cooperative agreement states that "JHU/APL will design and fabricate a high fidelity proof of concept testbed using as many state-of-the-art off-the-shelf subsystems as possible integrated with a newly developed controller and newly developed interfaces". This report documents the work performed to meet that Statement of Work and is organized similar to the Phase I report deliverable and with the RESEARCH TECHNICAL REPORTING REQUIREMENTS found at http://mrmc-www.army.mil/ and following the Research Reports links.

3 Military Need

The changing face of military missions, including the threat of biological and chemical warfare and increased accuracy and lethality of weapons, compels the US military to review and enhance its response capabilities.

Medical equipment and supplies must be reconfigured in order to meet the evolving and unique requirements of a rapidly deployable US military force while maintaining a level of support equivalent to civilian medical care. That is, medical equipment must be small, lightweight, inexpensive, rugged and totally responsive to the needs of the injured soldier – capable of being delivered to the far forward early trauma scene and easily operated by medics or other available personnel. Greater evacuation distance to medical facilities and reduction in forces require the devices to operate long enough to transport injured soldiers out of the operational environment and provide sophisticated life support until definitive surgical or medical care can be rendered. Of critical importance are efficient methods of bleeding control, airway management, and fluid therapy initiation.

The battlefield environment dictates this equipment must be safe, rugged, small, and easily portable; traditional far forward health care capabilities consist of very minimal equipment sets and capabilities. Empowering medics with sophisticated equipment and diagnostic capability while maintaining the lightweight, portable standards necessary for US military deployment would greatly improve the survivability rates for battlefield injury.

4 DESIGN RATIONALE

The need to develop strategies to rapidly deploy forces to protect US interests has sparked remarkable and dramatic changes in the orientation of the US military, specifically the US Army, since the end of the Cold War. These efforts attempt to address the need for highly

mobile, deployable forces and support equipment, such as improved computer capacity for rapid, accurate information dissemination and logistical deployment coordination.

Enhancing the medical capabilities of deployment troops requires far more than just modifying or extending conventional medical equipment and devices. To wit, the traditional field hospital or Deployable Medical Hospital (DEPMED) facilities no longer can keep up with the rapid pace of battlefield deployment, particularly in terms of resuscitation and transfer of critically injured soldiers. A large majority of the casualties that lead to death on the battlefield could be mitigated by treatment in the early minutes after injury. Nearly 70 percent of deaths resulting from battlefield injuries occur within the first hour; the Joint Health Service Support (JHSS) Vision 2010 states, "The single most critical time for treatment of a casualty is the first ten minutes".

Clearly, greater and greater casualty care needs to be focused on the early, pre-hospital environment where often medic or non-physician medical personnel provide the only medical assistance. Unlike civilian casualty scenarios where evacuations can occur within minutes, security issues on the battlefield may prolong evacuation, and access to traditional medical treatment may be additionally constrained by substantial distance from hospital facilities. For example, during Operation Desert Storm the highly mobile combat operations increased the span of evacuation and strained the efficiency of medical transport platforms. Accordingly, the ability to diagnose, restore and resuscitate severe battle trauma soon after the casualty and provide enough stabilization time, often an hour or more to allow for patient transport to definitive care, is of paramount importance.

Primary requirements for treating battle trauma revolve around diagnosing those reversible conditions that can be effectively treated and sustained in the early minutes after injury. These include (1) identify and control bleeding site(s); (2) treat severe hemorrhagic shock, and (3) reduce morbidity related to secondary events such as pulmonary embolus or fat emboli through the stabilization of fractures or pelvic injuries; and (4) treat respiratory failure resulting from penetrating injury to the thorax, causing bleeding in the thorax or collapse of the lung due to air entering the thorax, air or blood entering the pericardial space, or disruption of those internal structures resulting in impairment of ventilation. In general, soldiers treated for shock after severe hemorrhagic injury may need to be mechanically ventilated. Currently, mechanical ventilation is not performed as a routine procedure in the very far forward field environment. Historically, this lack of care has resulted in significant mortality.

The impact of unconventional weaponry must be considered in battlefield medical doctrine. Soldiers exposed to chemical or biological weapons may experience acute or sudden respiratory paralysis requiring mechanical ventilation. Respiratory paralysis may occur suddenly following exposure to organophosphorous chemical agents or more insidiously from paralytic agents such as Botulism toxin, or as pneumonia following exposure to Anthrax. Although exposure to certain chemical weapons may require only temporary ventilatory support, it must be available in the forward environment where exposure is likely to occur. During a biological weapon strike, immediate respiratory support could be essential for survival. This may become one of the most significant and important applications for the FFLSS in future conflicts.

Currently, there is no operational field ventilator, mechanical ventilator, oxygen supplies or other sophisticated monitoring available to far forward medics. The large and cumbersome far forward surgical treatment facilities do not provide the early venue of care often necessary after acute penetrating injury or hemorrhagic injury that occurs on the battlefield. For these reasons, a major effort over the past 5 or 6 years at the research commands of the US Army, Air Force and Navy have focused on developing alternative strategies and techniques to improve very early far forward care of battle trauma.

In the early 90s, the US Army, in cooperation with the DARPA, instituted a program to develop the Life Support for Trauma And Transport, LSTAT, an encapsulated trauma stretcher capable of delivering life support in terms of oxygen ventilation, mechanical ventilation, critical care monitoring, IV fluid infusion, drug infusion and data logging capability compatible with traditional military transport vehicles and aircraft. The LSTAT program has received considerable support from the Army and the US Congress and is now in advanced stages of deployment and testing within the US Army. However, in that it comprises the footprint of a standard stretcher and requires 4 individuals to carry a single patient. While the LSTAT could be brought in with a helicopter, Humvee or other transport vehicle, it is not likely to be carried as part of a standard kit of medical care capability by an operational medic working the far forward environment. This prevents it from being widely deployed during the very early moments after trauma, where medical intervention is most critical.

It is possible to conceive of a device for mechanical ventilatory support that would include easy access to the respiratory tree through nasal pharyngeal intubation or mask intubation. However, Ambulatory (AMBU) Bag respiration and ventilation is notoriously inefficient and requires constant participation thereby restricting medics from treating other casualties.

An ideal far forward respiratory device that assists medics in the care, stabilization and subsequent transport of severely injured trauma patients would include a rudimentary mechanical ventilator capable of sustaining modest ventilatory requirements for approximately an hour in a stand-alone, battery-powered mode. The ventilator should be capable of both assisted ventilation and complete mechanical ventilation with a variable ventilatory rate and optional oxygen delivery. Ideally, the ventilator would be extremely lightweight and portable, yet rugged, and contain necessary sensor devices to assist in regulating ventilatory function and/or provide direction regarding the efficacy of ventilatory therapy.

The Far Forward Life Support System (FFLSS) is designed to meet these requirements. In particular, its small size and footprint facilitates quick delivery to the very far forward combat injury environment. A weight of approximately 18 pounds enables the FFLSS to be easily incorporated as a component of standard equipment on general transport vehicles. Fully automated and simple to operate, the FFLSS requires very minimal operator intervention to adjust settings and regulate ventilatory capacity. The device is designed to provide a minimum of one hour of battery-powered operation; it has an optional oxygen delivery system, suction to keep the airway open, particularly critical in cases of high levels of secretion that could occlude or impair ventilatory capability, and intravenous fluid warming capability to optimize temperatures. Essential sensor arrays include a pulse oximeter, end-tidal capnograph, and an

estimate of blood pressure. The FFLSS is the only device that fulfills military medical requirements, and provides basic respiratory care during the critical hour following injury.

5 DEVICE DESCRIPTION

5.1 Overview

The consensus requirements for an effective FFLSS are summarized below.

1. The FFLSS should adapt to multiple transport and logistical scenarios including medic transport, armored transport, aviation systems and operate within the constraints imposed for far forward operations.

2. The FFLSS must be portable and lightweight (under 25 lb).

3. The FFLSS should be self-contained, with an autonomous architecture that provides a simple, low cost, first responder apparatus for initial patient data acquisition. As the system advances, the data gathered by the sensor system should allow digitally controlled optimized care to the patient.

4. The FFLSS should continuously record selected patient data and then provide that data to other medical care systems after the patient is transported to a field hospital or other similar location.

5. The FFLSS should remain self-contained and operational for a minimum of one hour with no additional power.

6. The FFLSS should provide a low-power, lightweight ventilator system. Future systems should provide an integrated controller capable of digitally controlling the air compressor and ventilator to optimize patient care.

7. The FFLSS should provide an integrated pulse oximeter to measure oxygen saturation in the blood stream. The data would provide feedback on the effectiveness of ventilation efforts or the patient's own respiration.

8. The FFLSS should integrate a capnograph to measure breathing effectiveness, endotracheal tube (ETT) placement, and hyperventilation controls.

9. The FFLSS should integrate an IV fluid infusion pump to deliver fluids into the patient to manage the effects of shock.

10. The FFLSS should provide a suction capability.

The following chart appeared in the Phase I final report and served as the starting point for this design. ECG and Infusion Pump Display are functions that were deleted at the

conceptual design review held in December, 1999 with internal and external technical personnel from WRAMC (GOR Dr. Frederick Pearce), ECRI, Infusion Dynamics, Biostar, and Dr. Jonathan Newell.

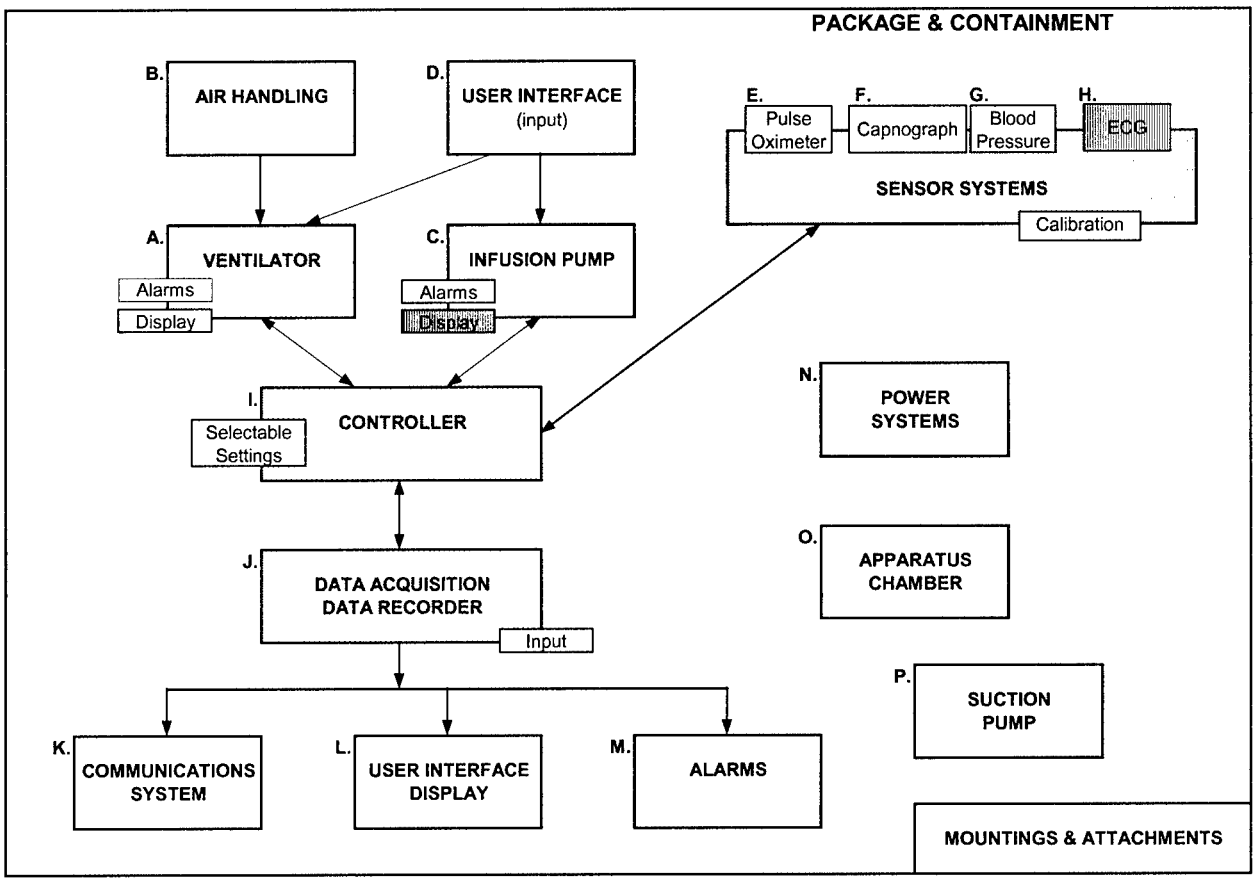

Figure 1 FFLSS Concept Block Diagram

The following sections will address each of the subsystems seen in this chart and will provide information on:

- Controls, operating range of controls, and dependence on other controls
- Monitored data including the parameters, sensing mechanisms and detection ranges, and associated alarming capabilities.
- Threshold levels and alarm limits for alarming capabilities
- Modes of ventilation and characteristic waveforms.
- Backup ventilation parameters and characteristics (default parameters)
- Display ranges with resolution
- Default values for each ventilator control, limiting and alarm parameter.

5.2 Ventilator

The ventilator circuit was tested using a Michigan Instruments (Grand Rapids, MI) Model 2600 Dual Adult test lung. This calibrated system includes Pneuview software to calculate and graph all ventilator performance parameters. It was used as our 'gold standard' when calibrating FFLSS ventilatory parameters.

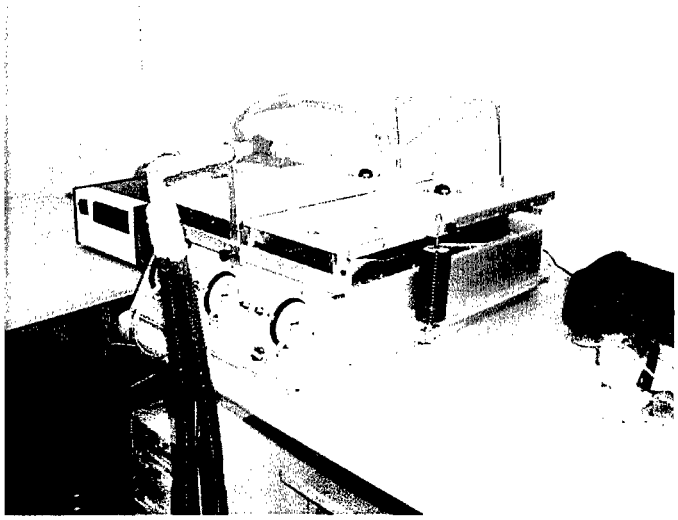

Figure 2 Michigan Instruments Model 2600 Dual Adult Test Lung

The Phase I study chose a small air compressor (over other technologies) as the prime air mover in the system. For the Phase II prototype, we chose a Sensidyne (Clearwater, FL) C series dual head, diaphragm, micro air pump (CD120INNN). Peak inspiratory flow into the test lung with airway resistance set at 5 cmH20/L/sec and compliance set at 0.05 L/cmH_2O was in excess of 20 LPM . Note that this compressor is a constant flow device and *not* a constant pressure device.

With the above conditions, the compressor produces less than 0.5 psi. After much searching, no suitable electrically controlled valve for the ventilator circuit could be found for this low pressure and low flow application. The weight and in-line resistance of the commercially available valves were high. The solution was to use a ventilator circuit which includes a pneumatically controlled exhalation valve (Allegiance, McGraw Park, IL, Airlife Ventilator circuit with exhalation valve).

The entire block diagram is seen in Figure 3. Air is drawn in through a standard Army gas mask filter (3M, C2A1 NBC) by the compressor. The compressor output goes through an optional proportional flow valve (see Appendix). This allows the processor to adjust the flow down during inspiration. After the proportional valve, a small tube is connected to the mushroom exhalation valve with the main flow going through the flow sensor to the patient. A small mechanical mixing device was provided by Scott Aviation, the oxygen generator manufacturer. Oxygen from the COTS generators (4-6 LPM) can be mixed with the compressor output (max 20+ LPM). A fixed mechanical pop-off valve protects the patient from overpressure and vents at 106 cmH2O.

The scissor valve is normally open but is energized (closed) when the compressor is actuated during inspiration. When the compressor is turned off, the scissor valve is de-energized allowing pressure to bleed off the mushroom exhalation valve, thereby opening the patient expiration circuit. This is a workable solution, but makes implementation of Positive End Expiratory Pressure (PEEP) possible but problematic.

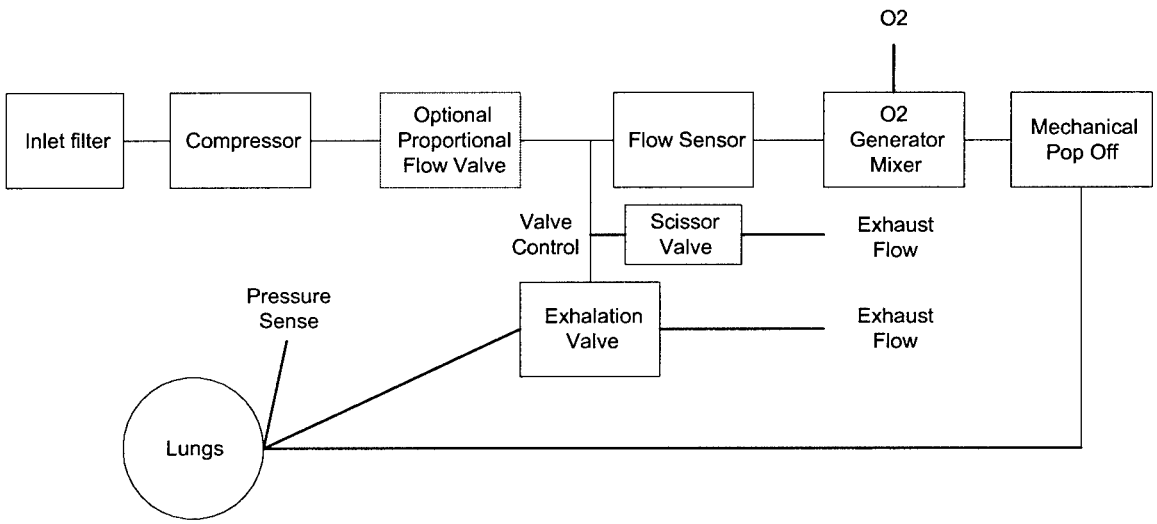

Figure 3 Ventilator Circuit with Scissor Valve

A two-way miniature rotary compressor (Fluid Power Inc., Owings Mills, MD) can be used to control the exhalation valve. This configuration decouples the control of the exhalation valve from the compressor operation which adds flexibility to the ventilator control modes. The final ventilator circuit block diagram is shown in Figure 4 below.

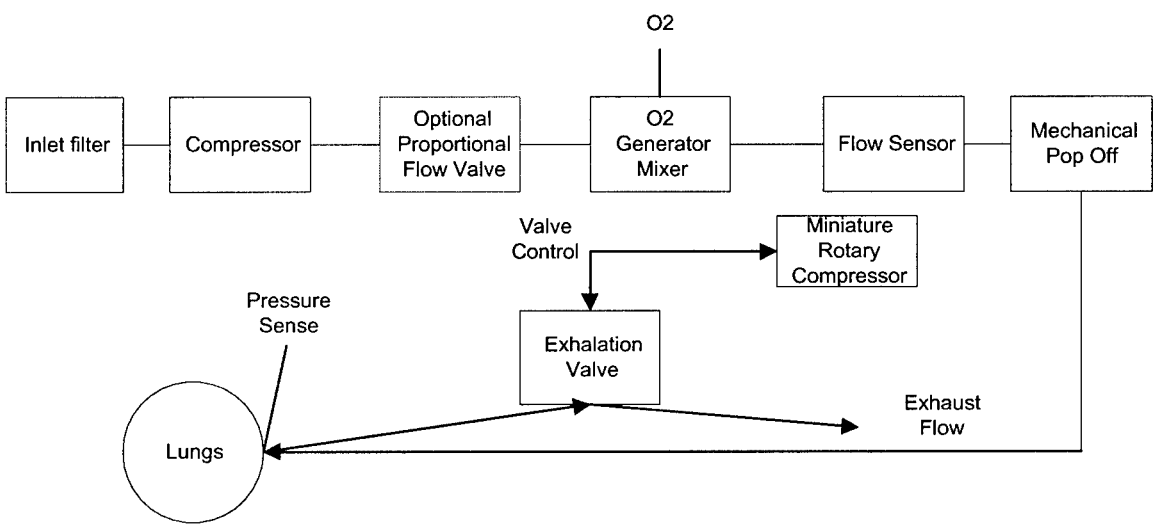

Figure 4 Ventilator Circuit with Miniature Air Compressor

5.3 Patient Connection

Standard ventilator circuits, single or dual, with integral exhalation valves can be used with the FFLSS. A dual circuit (Allegiance, OY3770 Ventilator circuit with exhalation valve, McGaw Park, IL) was chosen for testing. Note that when PEEP is implemented in software, no universal adapter and additional PEEP valve would be necessary. The FFLSS processor implements PEEP by direct control of the exhalation valve.

5.4 IV Fluid Pump

This IV Fluid pump is a Commercial Off the Shelf (COTS) product from Infusion Dynamics (Plymouth Meeting, PA). The following information is used with permission from their website. The Power Infuser™ is the first portable electronic infusion pump designed specifically to deliver crystalloid and colloid IV fluids to restore blood pressure and intravascular volume. Small, rugged and easy-to-use, it is equally comfortable at the scene of an accident, in an ambulance, or in the operating room.

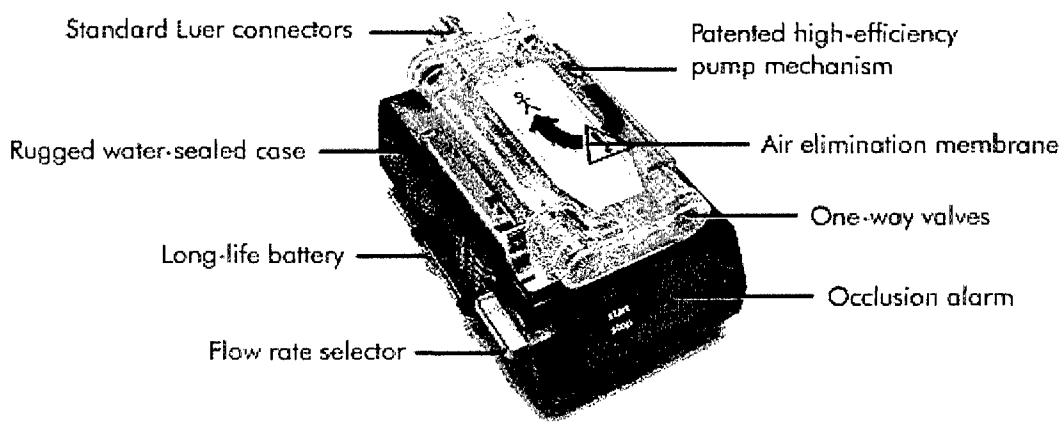

Figure 5 IV Fluid Pump

Figure 6 IV Fluid Pump on Patient

FEATURES: Flow rates can be adjusted between 0.2 and 6 liters per hour using a simple knob on the side of the pump - no IV bag elevation or pressure infusers are required. The Power Infuser also includes a range of sophisticated safety features: in-line air elimination membranes, a downstream occlusion sensor, and one-way valves to prevent backflow.

RAPID BOLUSES. When set to BOLUS the pump will infuse a volume of approximately 250ccs in just 2.5 minutes each time the start/stop button is pressed.

FREE FLOW. When the IV bag is elevated above the patient, fluids will free flow through the cartridge. Use this feature to generate a flow rate lower than 200 cc/hour, or to continue infusion once the pump has been disconnected.

AIR ELIMINATION. A series of hydrophilic and hydrophobic membranes are built into the cartridge to vent any air in the IV line before it reaches the patient.

In the field, the battery-powered pump can be placed on or near the patient for life-saving fluid resuscitation in situations where a lack of manpower or room to elevate the bag would normally impede treatment. Better control over flow and volumes delivered can improve adherence to local protocols and ensure adequate, but not excessive, hydration.

Power Source

12-15 VDC battery or adapter
Power consumption @ 6 lph <1 W
Weight (pump and arm strap) 220 gms
Dimensions (pump) 3.5x2.8x1.6 in or 8.8x7.0x4.0 cm
Weight (packaged) 265 gms
Dimensions (packaged) 5.0x4.0x2.3 in or 12.7x10.2x5.7 cm

Weight (single cartridge and IV set) 30 gms
Dimensions (cartridge) 1.8x3.8x0.5 in or 4.6x9.7x1.3 cm

Battery

Type Alkaline, non-rechargeable
Voltage 12 VDC
Capacity 500 mA-hrs
Battery life @ 6 / 2 / 0.2 Lph is 5 / 11 / 24 hrs
Weight (single battery) 60 gms
Dimensions (single battery) 3.3x2.1x0.4 in or 8.3x5.4x1.0 cm

For more information visit http://www.infusiondynamics.com/powerinfuser.html.

5.5 User Interface

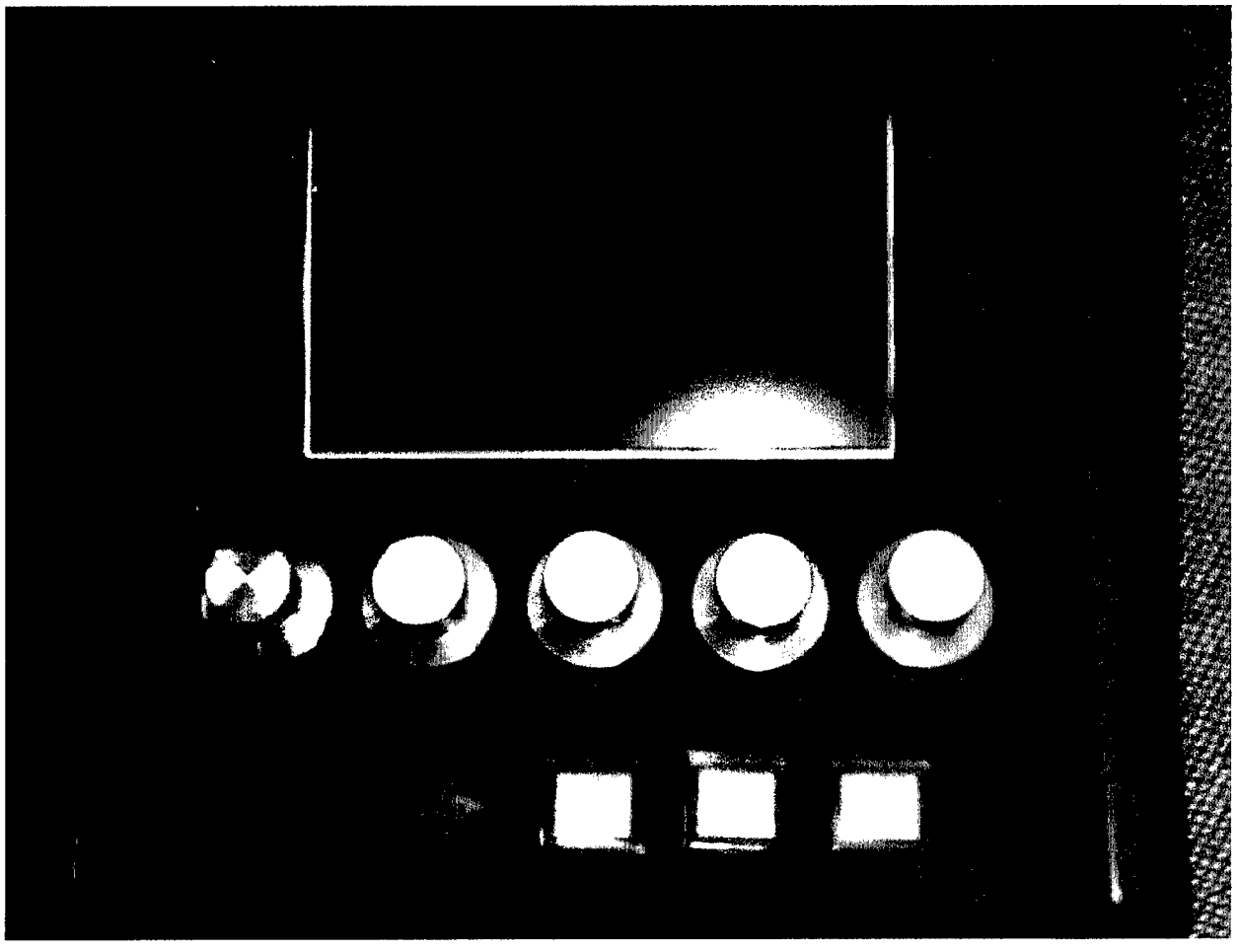

Figure 7 FFLSS User Interface

The FFLSS software was designed to enable the user to control the following parameters through use of 5 knobs:

1. **Volume** – The Volume of air that is delivered by the ventilator per breath, given in mL. The volume knob has a range of 0 – 2000 mL, with the default setting at 700 mL. Given that no other parameters have settings to cause errors (as described in the later parameter descriptions), the compressor will be active until this volume is reached during each breath.

2. **BPM** – The Breaths Per Minute (BPM) rate of the ventilator. The BPM knob has a range of 0 – 60 BPM, with the default setting at 10. Given that the set volume has been reached, the ventilator will set the expiration time in order to achieve the desired BPM. The Volume parameter has higher priority, and can lead to an inability to deliver the

desired BPM because following the delivery of the set volume, a breath is not done until the pressure during exhalation reaches a minimum value (set by the PEEP parameter described below). If the desired BPM is too high for exhalation to occur properly, then the ventilator will deliver the highest possible BPM and displays the difference between this "actual" BPM and the desired "set" BPM. When the actual BPM does not match the set BPM, an error is displayed to the screen.

3. **PEEP** pressure, when enabled.

4. **Pmax** – The Maximum Pressure reached by the ventilator, given in cmH_2O. The Pmax knob has a range of 0 – 80 cmH_2O, with the default setting at 80 cmH_2O. The Maximum Pressure parameter has higher priority than the Volume parameter, thus the compressor will be turned off if the Maximum Pressure is reached, regardless of how much volume has been delivered. If this occurs, two errors are displayed on the screen: "Max Pressure Reached," and "Volume Not Reached."

5. **PlotMode** – The PlotMode knob controls the graphing mode of the display. The user has three choices: Pressure, Flow and CO_2 Level measured from the capnostat. The default setting is Pressure. The plot mode can be changed at any time, though the axis labels will not be updated until the plot starts from the beginning again.

The knobs will have a user confirm feature. A knob can be changed and the display will change, but the change won't be implemented until the user confirms by pushing the Confirm Update pushbutton.

Ventilator Mode – The mode in which the ventilator is operating. When set to "Assist Control Mode (ASM)," the ventilator will start a breath when patient attempts to breathe, or when a certain amount of time (determined by the BPM setting) has passed by.

The five buttons have both color and text control.

The FFLSS wakes up with the display seen in the top line (Level 1) of Figure 8. Pushing the **Ventilator Stopped** button causes it to display **Ventilator Running** and the ventilator turns on. Pushing the **Ventilator Running** button turns the ventilator off and the button displays **Ventilator Stopped**. Pushing the **TAKE BP** button causes a blood pressure measurement to be taken. Pushing the **!** button will clear audible, flashing, or constant red alarms. Pushing the **Config** button drops down to the Level 2 menu (bottom line of Figure 8). In Level 2 and 3, pushing Return always returns the buttons to the Level 1 menu.

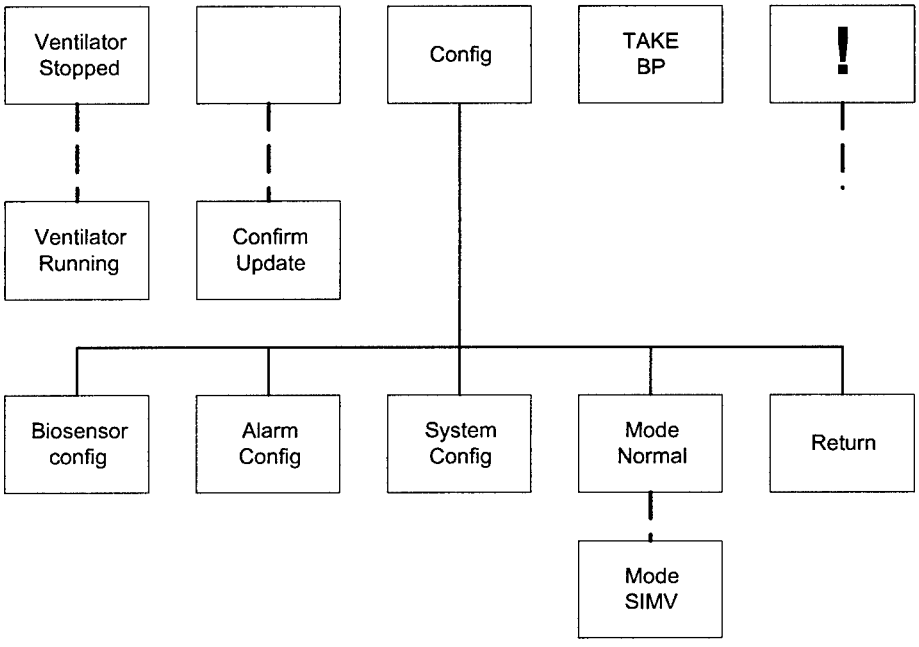

Figure 8 Levels 1 and 2 Display

Pushing the **Biosensor config** button drops down to Level 3 Part 1. The three sensor buttons can then be used to cycle them on and off. Pushing **Return** goes to the Level 1 menu.

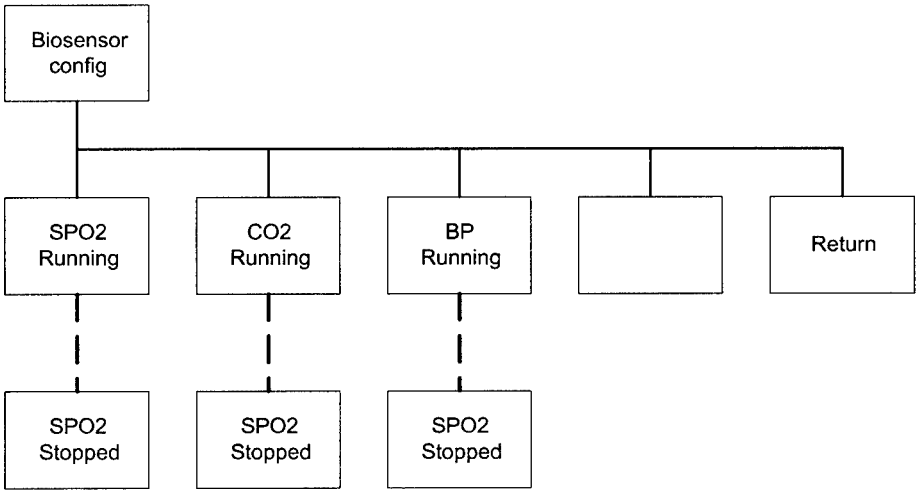

Figure 9 Level 3 Part 1 Display

Pushing the Alarm Config button on Level 2 drops down to Level 3 Part 2. Here the CO_2 error can be enabled or disabled. When testing with a test lung, there will be no CO_2 present and this error will continually go off unless disabled. The audible alarm can also be enabled or disabled. Again, with testing this audible noise can be disabled. The visual flashing or constant red cannot be disabled. Pushing **Return** goes back to Level 1.

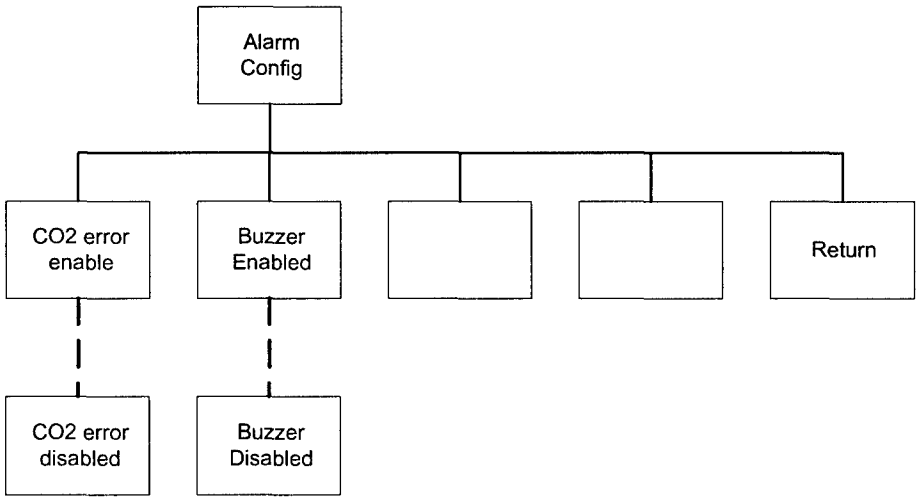

Figure 10 Level 3 Part 2 Display

Pushing **System Config** drops down to Level 3 Part 3. The **DIMMER** button can be used to dim the LCD display backlight. PEEP can be enabled here and the PEEP value will be displayed above the center knob and is user adjustable. When the ventilator is stopped, the pressure sensor can be zeroed. Pressure **Zero Pressure Sensor** during an inspiration causes system stability issues. **DUMP DATA** will cause all data in memory to be dumped to an unused serial port on the UART. Pushing **Return** goes back to Level 1.

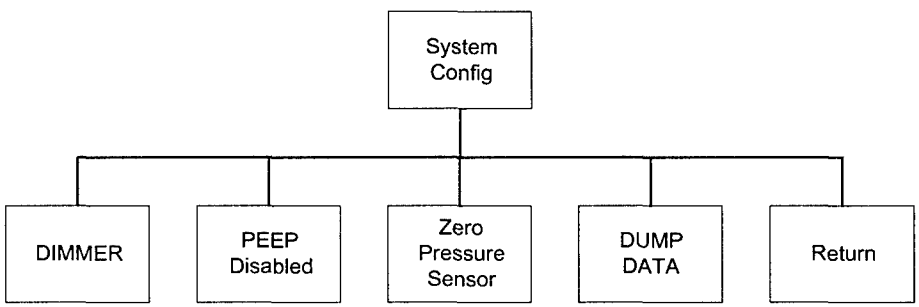

Figure 11 Level 3 Part 3 Display

Pushing the **MODE Normal** button on Level 2 causes it to display **MODE SIMV** and the ventilator changes to a SIMV mode.

5.6 Pulse Oximeter

Pulse oximetry is a straightforward and COTS sensor for medical monitoring. This sensor measures the patient's pulse rate and the oxygen carrying capacity of the patient's blood. Current standards of care only require the current values for the heart rate (HR) and oxygen saturation (SpO_2) levels; however, a pulse oximeter device is capable of measuring a

plethmograph wave – the actual beat-to-beat variation in the oxygen saturation level. The FFLSS uses the NONIN (Plymouth, MN) pulse oximeter. Figures 12 and 13 show the Nonin Pulse Oximeter Board and Sensor.

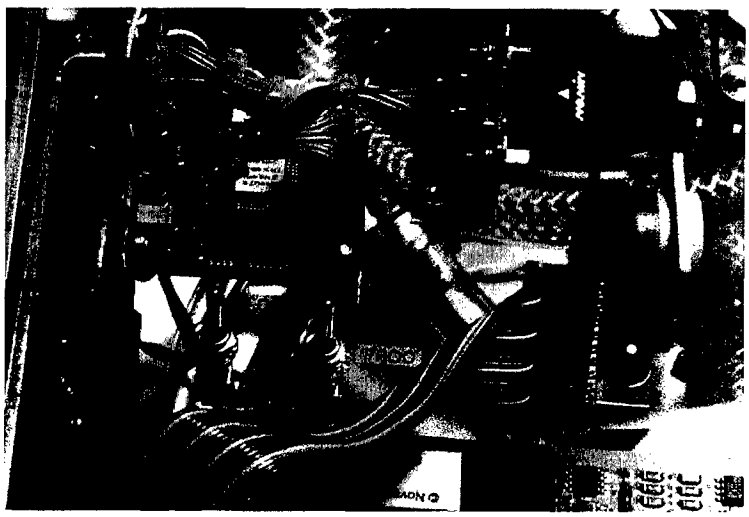

Figure 12 Nonin Pulse Oximeter Board

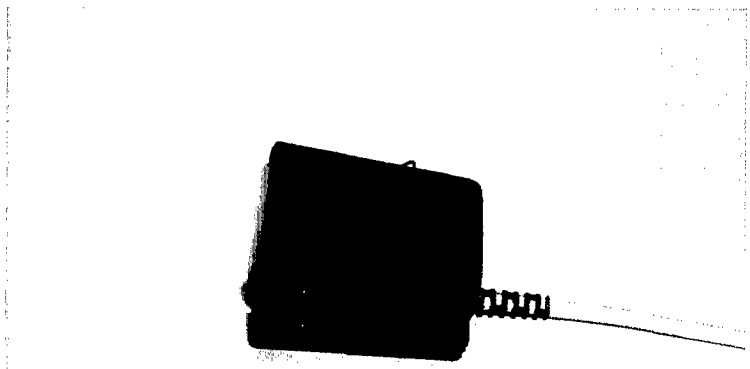

Figure 13 Nonin Pulse Oximeter Sensor

5.7 Capnograph

A capnograph measures the CO_2 levels in the patient's exhaled breath in one of two ways: (1) An optical sensor is placed in-line with the ventilator breathing circuit or, (2) an air pump "side-samples" air drawn from the patient's breathing path. In all cases, the sample is taken from the exhalation path if a dual path ventilation circuit is used. The respiratory rate can also be measured by the waveform generated by the capnograph. The capnograph is used to

verify the proper operation of the ventilator: lack of exhaled CO_2 indicates that the patient has apnea, the endotracheal tube is in the esophagus, or the patient has expired.

The unit installed in the FFLSS is the Novametrix, (Wallingford, CT) OEM $ETCO_2$ with the Capnostat III CO_2 sensor. Figures 14 and 15 show the Novametrix CO_2 board and sensor.

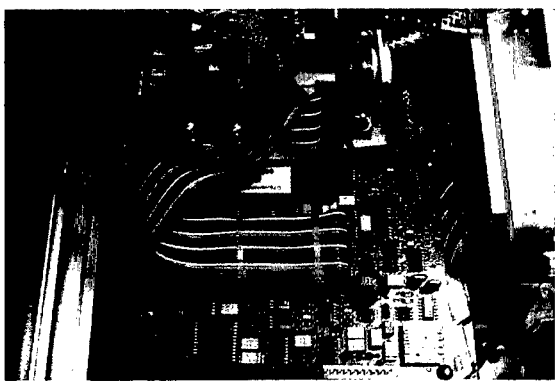

Figure 14 Novametrix CO_2 Board

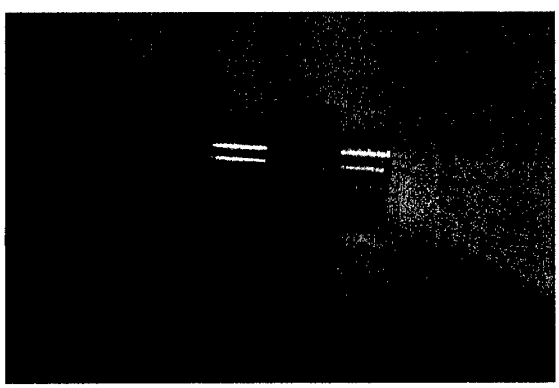

Figure 15 Novametrix CO_2 Sensor

5.8 Blood Pressure Monitor (BP)

A non-invasive blood pressure measurement (NIBP) is another important sensor. A typical NIBP system is a self-inflating BP cuff with pressure transducers for performing the auscultation function. The cuff inflates at regular intervals (~2 minutes). This unit, shown in Figure 16, is from CAS Medical Systems, Branford, CT.

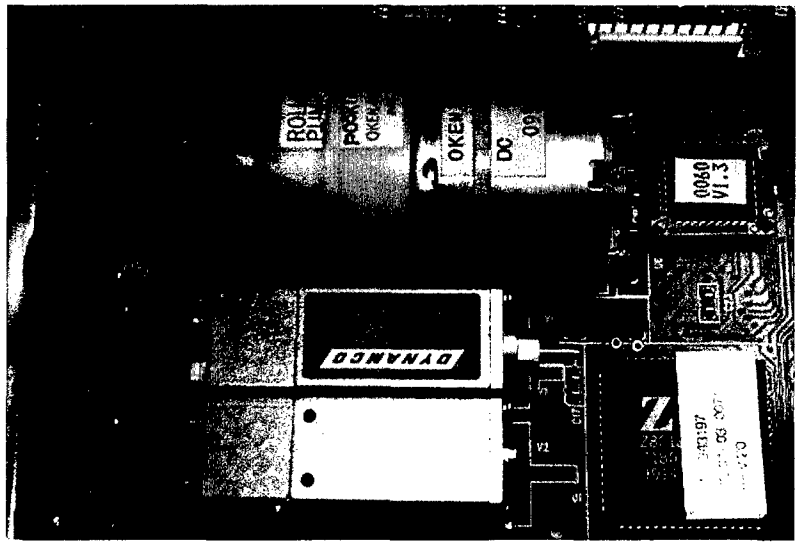

Figure 16 CAS Medical Blood Pressure Board

5.9 Controller

5.9.1 Processor

The processor system must be sufficient to perform the following tasks.

1. Acquire data from the attached sensor systems. This may include sending command and control signals to operate the sensor directly, or the sensor's control electronics, and to retrieve data generated by the sensor.
2. Have direct control over systems that do not have independent control electronics (e.g. the ventilator, operation, control, status, and settings).
3. Store data received from sensor systems and internal operational feedback.
4. Warning (alarm) personnel of a system problem, or a critical change in the condition of the patient.
5. Provide a means for personnel to set parameters of patient care and adjust those parameters as the patient condition changes.
6. Transfer stored data to additional medical support systems as the patient is transferred from FFLSS support to more definitive care.

In the long term, if the processor system could have the capability to adjust parameters based upon sensor data, personnel treating casualties would be freed for the most critical tasks, allowing the system to make the necessary minor adjustments for patient care in changing conditions.

The requirements for the processor (controller) board are:

1. Analog I/O for reading airflow sensor, air pressure sensor, pressure sensor power, battery voltage.

2. 4 Serial ports for communications, pulse oximeter, end tidal CO_2, blood pressure.

3. Digital I/O excluding memory: outputs to relays and other outputs

4. Memory: internal and external RAM, internal EEPROM, external ROM

5. Processing Speed: The worst case control loop will be for a potential flow control valve that is adjusted during inspiration. At 20 BPM and a minimum I:E ratio of 1:3, the inhalation control loop would last 750 ms. For 20 valve adjustments and 30 instructions per adjustment with 3 clock cycles per instruction, one needs 1800 cycles in the 750 msec period or 416 microseconds per cycle.

Our feasibility study for using commercial processor boards from Zworld, Axiom Manufacturing, and others found none of the commercially available boards, even with expansion I/O and relay cards, met all of the FFLSS requirements. Maintainability of the FFLSS units was a key point in the evaluation. If a commercial manufacturer discontinues or changes a product, a major redesign might be necessary for the system. An in-house design would allow modifications as necessary. Therefore, a custom processor board was designed.

The initial prototype under the FFLSS Phase I project used a Motorola MC68HC11. The HC11, the HC12, and the Motorola MC68336 were considered for this phase. The latter two have sufficient processing power for this prototype. While the 68336 has a 10 bit A/D converter and 16 analog channels, it had more processing power than the system required. The HC12 has 8 analog channels and an 8 bit A/D.

The HC12 with an 8 MHz system clock and 8 analog input channels was chosen for the processor board. This board also contains a Field Programmable Gate Array (FPGA) for glue logic and timing signals, a PIC controller for writing text to the pushbutton switches, a 4 channel UART for the serial ports, 128K RAM, 32K ROM, eight relays Non-Invasive Blood Pressure (NIBP), pulse ox, compressor, communications power, 2 O2 generators, suction, exhalation valve), and input conditioning circuitry. The schematic for this board is in the Appendix.

5.9.2 Software Overview

As one would expect, relatively extensive software is required to implement the many functions of the FFLSS. This section is a general outline of the software, and will assist in the understanding of the controller operation. Architecture, operational flow, and brief descriptions of the support functions and device drivers that were designed specifically for the project are discussed in sufficient detail to provide a general understanding of FFLSS operation. Full source code of the FFLSS software is included in the appendix of this document.

5.9.2.1 Main Program

After calling the initialization routine, the main program consists of one continuous loop, which performs all of the necessary user interface functions. The simplified main program flow is diagrammed in Figure 17.

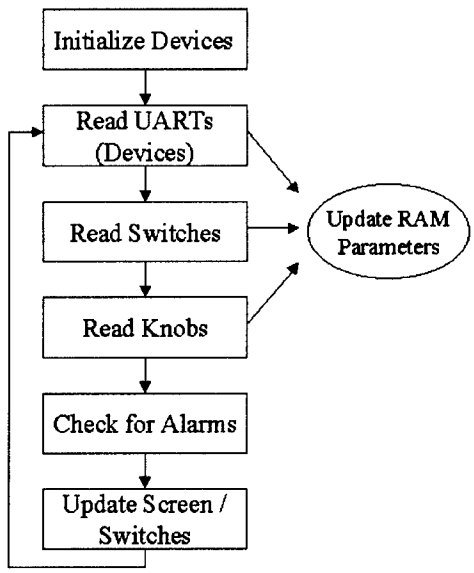

Figure 17 Simplified Main Program Flow Diagram

The main program has a particularly simple flow. First, several routines are called which read the output from the COTS biomedical sensors and update the appropriate static variables in RAM. At any time, any section of the code can read the RAM to ascertain the most recent vital signs from the aforementioned sensors. These vital signs include systolic and diastolic blood pressure, end-tidal CO_2, current CO_2 concentration, PAO_2, and heart rate. As the rate of execution of the main program loop is expected to far exceed the mean reporting rate of each COTS sensor, each output byte from each sensor will quickly be interpreted, and its appropriate holding variable will be updated. After reading the UART for bytes from the COTS sensors, the main program loop then calls routines to read the state of the switches and knobs. At that time, any necessary changes to the current ventilatory parameters, or other FFLSS modes will be made. After reading all of the input devices, the main program checks the current values of several ventilator variables. Alarms will sound if these variables exceed their desired ranges. An important feature is an Accept Change display. The user must push another button to confirm the change before the controller implements it. Finally, the main LCD display, and switch LCD displays are updated to reflect changes in the ventilation settings and performance. This is not done every time through the main loop, but only approximately 3 times per second using a time signal from the timer interrupt service routine.

5.9.2.2 Timer Interrupt Service Routine (ISR)

While the main program loop handles much of the user interface, the timer interrupt service routine controls the ventilator. This routine, which will be triggered every 10ms by the

68HC12's built in timer, keeps track of the current time per breath, the delivered volume, and the current breath, and is responsible for turning the compressor and/or exhalation valve on or off to deliver breaths to the patient.

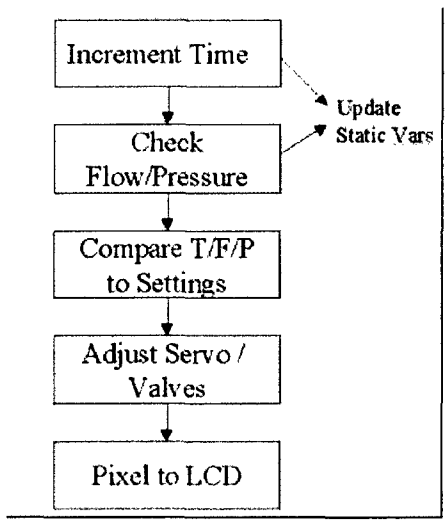

Figure 18 Timer Interrupt Service Routine Simplified Flow Diagram

As indicated in the Figure 18, the timer interrupt service routine updates and references a wide variety of static variables. Since this routine is called every 10 ms, the static variables provide the ISR and the main program loop with the information that indicates where the program is in the breathing cycle. Some of these parameters are current pressure, maximum pressure, current time, current flow, and current volume delivered. This routine sets flags that indicate to the main program loop that various alarm conditions are present. These conditions include no CO_2, inability to deliver desired volume, no pressure (check tube connection), overpressure, and inability to deliver desired breaths per minute. Finally, when the ISR notes that a complete breathing cycle has finished, some additional parameters are calculated: Minute Volume, actual I/E ratio, and actual Breaths per Minute (BPM). A flag is then set which tells the main program to update these parameters on the LCD display.

5.9.2.3 Device Drivers and Functions

As the FFLSS integrates a wide variety of sensors and user I/O devices, a wide variety of device drivers were written to simplify the main FFLSS software. Due to the multitude of these devices (including LCD display, Optical Encoder Knobs, End-Tidal CO_2 sensor, Blood Pressure Cuff, Pulse Oxymeter, airway pressure sensor, airway flow sensor, LCD pushbutton switches...etc.,) the device drivers and low-level interface functions are the majority of the software. A brief description of the routines written for each type of device follows.

5.9.2.4 LCD Display Support

Several device drivers were written to allow easy printing of text and graphics to the AND1021, a Toshiba T6393 controller based LCD screen. The LCD display unit accepts two different types of words from the processor: command words, and data words. **DSPCOM** and

DSPDAT were created to send commands and data respectively to the display. Both routines first read the status of the display controller to determine whether the controller is ready for another word. Once the display controller is ready, the routine sets the command / data line to the appropriate value and proceeds to write the command / data word.

Before using the LCD display, the T6393 controller on the LCD display unit must be initialized to set the screen size (graphics area and text area) and the location of each area in its memory map. The **INITDSP** function handles this, setting the display to the appropriate mode (Text + Graphics) and sets the sizes and locations of the text and graphics memories.

The display controller does not have a specific command to clear graphics or text. Two routines were written, **CLRDSP** and **CLRGRAPH**, to clear the text and graphics areas of the LCD display by rewriting the display RAM to all zeros.

The **WRITEDSP** function serves simply to write a null-terminated data string to the LCD display. The location of the string in memory, as well as the desired location on the screen are passed to this routine.

In order to make the FFLSS data display similar to that of a full featured ventilator, software routines were written to allow graphics to be written to the LCD display. These graphics routines create dividing lines on the screen, as well as plot pressure, volume, and CO_2 data for easy interpretation by medical personnel. The functions **PLOTPIXEL** and **PLOTLINE** provide easy graphics for any routine that needs them (in most cases the plotting routines called by the main program loop). Calling **PLOTPIXEL**(x,y) and **PLOTLINE**(x1,x2,y1,y2) is as simple as pushing the appropriate bytes (unsigned integers) onto the stack and jumping to the subroutine. Similarly, routines named ERASELINE and ERASEPIXEL are used to erase previously drawn graphics (this is done mostly by the function which handles the scrolling data graphs).

5.9.2.5 Optical Encoder Knob Support

Much of the interface to the optical encoder knobs is handled in hardware by an FPGA programmed for this purpose. In addition to a variety of board related glue-logic, the FPGA contains five independent 11-bit counters that keep track of the movements of each knob. By this method, the microprocessor only has to service the knobs fast enough to provide a reasonable response to the user, and does not have to catch every transition of the knob encoder line. Upon command by the microprocessor, the FPGA latches the contents of each of the five counters into one 55-bit long shift register, and the results are clocked out by a microprocessor provided clock. This function is handled by the routine **READKNOBS**, which is called each pass through the main program loop. After **READKNOBS** is called, the microprocessor calls **RESETKNOBS**, which sets all the knob counters on the FPGA to 400 Hex. Each knob ranges from 0 to 0x7FF in 10 turns.

The microprocessor keeps track of the current count at all times, and avoids FPGA counters overflow. Finally, the routine named **UPDATEKNOBVALS** updates the parameters in

memory that are controlled by the knobs. The scale and function also control the sensitivity of each knob.

5.9.2.6 Analog Airway Sensors

The airway pressure and flow sensors are both analog sensors whose value is accessed by reading the 68HC12's on-board A/D converter. The HC12 is put into continuous scan mode, where the latest value of the each sensor is available in the A/D result register. These registers are renamed in the source code to **PSENSORAD** and **FSENSORAD**.

A routine named **FLOWINTEGRATE** is called every 10ms from the Timer Interrupt Service Routine. This routine keeps a running sum of the results in the **FSENSORAD** register for each 10ms period. These results are interpreted by a routine named **FLOWEVAL**, which evaluates the number, scales it, and returns the total delivered volume for that breath (in cL). This value is used by the ISR to determine when to stop the inspiration phase of the breath.

Similarly, a routine named **READPRESSURE** is also called each time in the timer interrupt service routine. This routine measures the current pressure, and converts it to cmH20 for the ventilatory control system, and for display.

5.9.2.7 Serial Communication Support

Because of the large number of serial devices needed, a 4-channel UART was added to the FFLSS processor board. This device is memory mapped, and software routines were written to initialize, service, and utilize each channel. First, the routine named INITUART initializes the device for the following settings.

Channel	*Attached Device*	*Baudrate*	*Data Format*
A	SpO2	9600	8-N-1
B	NIBP Unit	4800	8-N-1
C	$EtCO_2$	9600	8-N-1
D	External Terminal	<Not Defined>	<Not Defined>

First-in, First-out (FIFO) buffers for each channel are enabled and reset. By this means, the main program loop can simply read the contents of each channel's receive FIFO each time through the loop.

Other functions written for serial communication support include **CLRFIFOA**, **CLRFIFOB**, and **CLRFIFOC**, which simply reset the associated FIFO in the UART, dumping any stored data (presumably erroneous).

5.9.2.8 COTS Vital Sign Sensor Device Drivers

During normal operation, all three COTS vital sign sensors (Pulse-Oximeter, Capnograph, and NIBP) will be placed in modes to operate independently. Specifically, each device will take measurements without processor intervention, streaming the results back across the UART. Functions were written to allow the HC12 to write the appropriate sequence of bytes to the devices in order to place them in these modes. These functions are currently named **WRITECO2**, and **WRITEBP** (the pulse oximeter automatically powers up in the aforementioned mode). Note that more features are added to the FFLSS, it is likely that these sensors will not always be operating in this mode. The NIBP sensor would be useful in several different modes.

On each pass through the main program loop, the HC12 checks the status of each UART channel to see if bytes have arrived from the sensor. If the UART indicates that a byte is present in the FIFO, that channel's data interpreter routine is called.

5.9.2.9 COTS Vital Sign Sensor Data Readers and Packet Interpreters

The **READCO2UART** function reads the CO_2 data from the capnostat whenever there is a byte in the EtCO2 channel of the UART FIFO. That byte is loaded, placed into a holding variable, and sent to the interpreter (ETCO2INT), which builds a packet. Upon completing a packet, the results are stored in the appropriate variables. Similar routines exist for the pulse-oximeter, and NIBP channels. They are named **READSPUART**, **SPO2INT**, **READBPUART**, and **BPINT** respectively. Each data interpreter routine, while building the packet, checks for errors or invalid formats. In the case of the ETCO2 sensor, a checksum is calculated. This is done by the **INTERP5** routine.

5.9.2.10 LCD Pushbutton Switches

The FFLSS utilizes five pushbutton switches for option selection and menu navigation. These switches, for flexibility and clarity, have integrated LCD displays on the button face. The transflective displays also have LED backlights that can be red, green, or yellow. The same FPGA used for the optical encoder interface drives the LEDs. A routine named DOCOLS handles the communication with the FPGA: the colors indicated in the variables COLOR1 – COLOR5 and DIMMER, are sent to the appropriate registers in the FPGA.

Similarly, the control of the LCD faces of the switches is delegated to a dedicated processor, a PIC 17C756 microprocessor. The routine **UPDLCDSWITCH** will communicate with the dedicated processor over a serial channel, telling the processor which screen to place on each of the displays. This routine is not currently implemented as of this writing; the software on the dedicated processor and the support driver will be described separately.

5.9.2.11 Utility Functions

Several functions were written which simply provide specialized services for the remaining software. A very brief description of these follows.

Byte2ASC takes a single byte unsigned value and converts it to a 4-byte null-term ASCII string to be printed on the display.

Byte24Dig is very similar to **BYTE2ASC**, except that it returns a 4 digit number with a decimal point in the middle.

ASCIIBinary function converts a 2 byte ASCII variable into Binary.

PRINTKNOBVALS routine prints the knob values to the screen.

DISPPRESSURE function calls **BYTE2ASC** to convert the pressure into an ASCII string and then displays the string to the screen by calling
WRITEDSP.

DISPVOLUME function calls **BYTE2ASC** to convert the volume into an ASCII string and then displays the string to the screen by calling **WRITEDSP**.

5.9.2.12 Scrolling Graph Support Functions

When the appropriate flag is set by the timer interrupt service routine, the main program loop calls a fairly self contained function named DOPLOT. This function maintains the operation of the on-screen scrolling graph of either pressure, flow, or airstream CO_2. Each time this routine is called, another pixel is placed on the graph. This function makes use of some subordinate functions, meant primarily for calling by DOPLOT. These routines are discussed very briefly below.

LABELPLOT puts labels onto the X and Y axes.

AXISPLOT plots the axis on the graph and draws the corresponding tick marks.

Throughout the design process, the software design team goal was to provide reliable and flexible software such that additional features can be easily implemented as the needs of end-users become more evident. This document describes the architecture and meaningful functions of the FFLSS prototype software. Using these descriptions and the FFLSS assembly language with source code comments (attached), the user should be able to completely understand (or even change) any aspect of the operation of the FFLSS.

5.10 Data Acquisition System

Data acquisition is accomplished using the eight analog inputs of the HC12 processor. Conversion time is approximately 2 microseconds per channel.

5.11 Communications System

The system must provide a mechanism by which the data acquired can be transferred with a patient as the patient moves through the tiers of medical care. Whether wired or wireless, the communication interface must provide connectivity with other systems currently in use with the military. This prototype has a spare RS-232 port in the UART that can be programmed to communicate with a communications system when defined.

5.12 User Interface Display

The display must enable personnel operating the FFLSS to evaluate a patient's current condition and medical trend. The display must also provide information and feedback necessary to change system settings influencing the care provided to the patient.

ECRI critiqued the initial integration of all subsystems and had the following inputs.

- Position knobs under sensors
- No spinning knobs
- No touch screen for adverse conditions or if it gets damaged
- Screen is somewhat cluttered
- More important things at top such as BPM
- Only necessary display graph is a gauge for pressure, unless four or more breaths are shown for flow or tidal volume
- Waveforms as back-up, pressure bar graph primary gauge
- Waveforms difficult to interpret and not important for field (important if shapes need to be monitored for errors such as when I:E changes)
- Overlaying screens not recommended, but if necessary, never more than one screen away from the home screen

Many of these inputs were partially or fully implemented. Figure 19 shows the actual screen display.

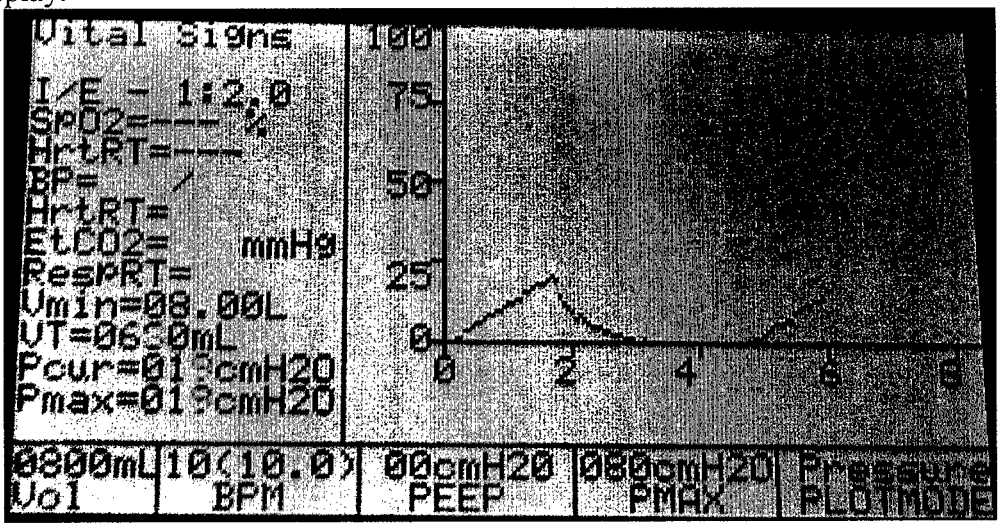

Figure 19 User Interface Display

5.13 Alarms

The FFLSS is designed for the battlefield environment and for the more traditional civilian hospital. Consequently, the alarm requirements are different. Many variables and failures can be alarmed, but the strategy is for a reduced default set of alarms. Alarms may be audible, visible on the user interface display or the lighted, text capable pushbuttons, and a TBD (wireless) remote.

Alarm Rules

- In general, all alarms will be audible and visible on the display and/or the lighted pushbuttons
- Audible alarms will be constant for critical conditions and beeping for non-critical conditions
- Audible alarms can be disabled by pushing the alarm pushbutton and will not resound for one minute to give the user time to clear the condition
- Audible alarms can be disabled, but visible cannot
- Visible red pushbutton alarm will flash for critical conditions and constant red for non-critical conditions
- Visible alarms will remain visible until the situation is corrected and the alarm pushbutton is pushed
- Alarms parameters can be set through simple menus
- Other alarms are possible for blood pressure, heart rate, carbon dioxide sensor, and the pulse ox sensor
- For testing, the CO_2 alarm can be disabled
- Future communications interface can transmit alarms

The FFLSS is designed to display the following error messages to the screen:

1. **BPM NOT REACHED** – Occurs when the ventilator cannot deliver the breath rate given by the BPM knob.

2. **MAX PRESSURE REACHED** – Occurs when the maximum pressure, set by the Pmax knob, has been reached.

3. **VOLUME NOT REACHED** – Occurs when the volume set by the Volume knob has not been reached. This condition could result from leaks in the breathing circuit or in unison with the "Max Pressure Reached" error.

4. **CHECK TUBE CONNECTION** – Occurs when no pressure is measured. This usually happens when the tube to the patient has been disconnected.

5. **NO CO_2 IS PRESENT** – Occurs when no CO_2 is detectable, either due to the tube connection error, apnea, endotracheal tube in esophagus, or death of patient.

6. **LOW Battery** - battery voltage is displayed and needs to be calibrated.

5.14 Power

The system must have sufficient power to operate for a minimum of one hour without additional power sources. Battery use should be optimized to minimize time required to refurbish the FFLSS unit between patients or deployments. The standard Army BA-5590/U battery was chosen to power the FFLSS. This battery has two 12 VDC $LiSO_2$ cells that can be wired in parallel for longer system life. This battery is rated at 14.2 A-hrs. Maximum current draw estimated for the system is 2.5 - 3 A will all sensors, ventilation and suction running.

5.15 Other Equipment And Spares

Oxygen generators from Scott Aviation (Lancaster, N.Y.) are optional source of non-bottled oxygen. They manufacture a standard cylinder that provides 4 liter/min of pure oxygen for twenty minutes. The Scott AVIOX Duo-PAK is a standard product that holds two oxygen generators. A small tube connects the Duo-PAK output to the FFLSS. A mechanical mixer provided by Scott mixes the oxygen and the compressor output just prior to the flow sensor. The oxygen generators can be hot swapped in the Duo-PAK, i.e. when one generator is exhausted, it can be removed from the Duo-PAK and replaced with a fresh one while the other generator is delivering oxygen. Scott supplied a simple mechanical mixer based on a venturi designed into one of their products to combine oxygen generator flow and the output of the compressor.

An early goal was to use the excess heat from the oxygen generators to help warm IV fluids. No reliable method was determined to maintain a constant IV fluid temperature over anticipated environmental conditions. Fluid heating will be a future improvement to the FFLSS system.

5.16 Suction Pump

The suction pump is a single-head, diaphram model from Sensidyne.

5.17 Operational Use

The system shall be designed to minimize any training that may be required to setup or operate the system. Displays and interfaces shall be simple, logical, easy to read and understand.

6 PACKAGING

The fielded version of the system shall be encased in such a manner that normal wear-and-tear will not cause the system to fail. The system packaging shall be designed to accommodate expected use.

A "production like" case for the Far Forward Life Support System (FFLSS) was designed in SolidWorks (Concord, MA). The design goals were to make a rugged housing for the FFLSS, fit all of the required components in the case and create a user-friendly interface. The first conceptual design was to modify an existing Pelican case and create a mold from which multiple cases would be produced. After investigating the problem of creating a "production like" case,

the modified Pelican case approach was abandoned because the desired result would not have been obtained. A new design was created completely in SolidWorks where a rapid prototyped model would be used to create the mold and then produce multiple copies using a poured resin material.

The case design included several challenges: foremost was the draft angles to all surfaces in the case to simplify the mold creation and extraction of the part from the mold. The arrangement of all the interior electronics, pumps, compressors, mufflers, and filters needed to be such that it minimized the overall footprint. Soundproofing needed to be fitted around the main air and suction compressors. The layout of the interface between the user and the ventilator needed to be determined.

Designing for a Mold

When designing a molded part, several key points were considered. First, to remove the cast parts from the mold, the parting line needs to be determined. Draft angles must be at least 1 degree from the pull direction. Wall thickness is important: if he walls of a molded part are too thin, the model may not fill completely. Conversely, as the walls of a part become too thick, pits and excessive shrinkage may occur. Inset surfaces and holes perpendicular to the plane are harder to mold, and should be minimized. Sharp corners make the removal of the mold from the molded piece difficult, so all intersecting planes should have a slight radius.

Placement of Internal Components

The electronics used to control the ventilator were condensed into a small package, locating all of the boards for power, control and measurement under the LCD screen and control buttons. For easy access to the components, the LCD and controls were placed on the lid of the box, leaving the processor and power boards within reach. The battery was placed in an easily accessible area on the front of the case, next to the handle. The main air compressor and suction pump were placed in a sound proof box molded into the case. The box is lined with leaded vinyl and foam, which acts as both a sound and vibration insulator. The air filter is located on the back right side of the case. The flow control sensor, pressure sensor and mushroom valve actuator were placed on top of the box. A manifold improves the interface for all external connections to the ventilator, i.e. the pressure sensor tube, CO_2 sensor, blood pressure, heart rate, O_2 tube, inhalation circuit, exhalation circuit, mushroom valve tube, and suction tube.

Manifold

The manifold was designed to simplify tubing and sensor connections, and to decrease the amount of space dedicated to the mufflers, tubing, pressure relief valve and O_2 mixer. External connections to the ventilator include the pressure sensor tube, CO_2 sensor, blood pressure, heart rate, O_2 tube, inhalation circuit, exhalation circuit, mushroom valve tube, and suction tube. In the original prototype, all of these connections were made while the case was open, and therefore, constantly exposed to the elements. The electronic components would need to be in a separate watertight case. A field portable model must have a watertight case. The new

manifold along with a face seal mating with a lip from the lid, satisfied the watertight requirement and also provided easy access to all needed connections.

The manifold simplified the internal tubing and incorporated the inlet compressor muffler, outlet compressor muffler, the O_2 mixer and the pressure regulation valve. The morass of tubing and these components required considerable amount of space in the original prototype. To reduce the amount of tubing, the inlet filter is placed directly in line with the inlet compressor muffler. From there, four connections from up to two main air compressors go to each inlet. Compressor(s) outlets go the to inlet ports on the manifold for the outlet compressor muffler. From there, two outlet ports go to the mixer. Currently, the pressure relief valve is an add-on to the manifold. The design goal is to incorporate this valve and the mixer into the manifold. The O_2 for the mixer would be drawn from the outside and other manifold entrances and exits, thus further reducing the amount of internal tubing.

Case Material

This case is built with a urethane material having a density of 1.16 g/cm^3. This density is a good compromise for weight, durability, and ease of molding. The urethane material system is compatible with a rubber mold. With glass transition temperatures for urethanes running typically from 160 to 200 degrees F, this case is good to only 120 F. Note that these decisions are for the prototype, and not a field ready unit.

7 DEVELOPMENT TESTING

7.1 Phantom Lung

The following information is reproduced from the manufacturer's website, http://www.michiganinstruments.com/Default.htm .

The Michigan Instruments (Grand Rapids, MI) PneuView® Dual Adult System offers unparalleled lung simulation and data collection capabilities. The Dual Adult lung incorporates two dynamic adult lung models with independently adjustable pulmonary compliance and airway resistance. This allows for simulation of a wide variety of healthy and diseased pulmonary conditions including unilateral lung disease.

The PneuView® software is designed to measure, display, and document the performance of mechanical ventilators as well as provide valuable insights into the dynamics of mechanical ventilation.

PneuView® Dual Adult Software Specifications - Model 2600i	
Working Range:	
Breath Rate:	2 to 100 bpm
Inspiratory Time:	.3 to 30 seconds
Expiratory Time:	.3 to 30 seconds
I:E Ratio:	as calculated
Tidal Volume:	100 to 2,000 liters
Minute Volume:	as calculated

Peak Inspiratory Flow:	10 to 200 lpm
Peak Airway Pressure:	-20 to 120 cmH2O
Peak Lung Pressure:	-20 to 120 cmH2O
Mean Airway Pressure:	-20 to 120 cmH2O
Baseline Pressure:	-20 to 120 cmH2O

Figure 20 Pneuview Dual Adult Software Specifications Model 2600i

Waveform Displays

- Volume
- Lung Pressure
- Airway Pressure
- Flow

Test Lung Specifications, Model 2600i	
Lung Capacity:	0 to 2.000 liters
Residual Volume:	.918 liters
Compliance Settings:	.01 to .15 L/cmH20
Airway Resistors:	Rp_5, Rp_{20}, Rp_{50} Rp_{200}, Rp_{500}
Size:	20"x25"x13" (51cm x 64cm x 20cm)
Weight:	37 lbs. (16.8kg)
Warranty:	2 year
Electronic Specifications	
Power Source:	9VDC, 500 mA Transformer provided with unit
Software Data Link:	db25 pin, female, parallel port
Auxiliary Output:	0-1 VDC, intralung and airway pressures

Figure 21 Test Lung Specifications, Model 2600i

7.2 Test Standards

The following are nominal standards for testing ventilators.

Normal Adult testing conditions
Compliance: 0.05 L/cmH_2O
Resistance: 5 cmH_2O/L/S
Tidal Volume: 500mL
BPM: 20

Abnormal Adult testing conditions
Compliance: 0.02 L/cmH_2O
Resistance: 20 cmH_2O/L/S
Tidal Volume: 500mL
BPM: 20

7.3 Ventilator Circuit Development Testing

Scissor Valve

The basic circuit is seen in Figure 3. When the compressor was turned off, the mushroom valve remained connected to the patient circuit and pressurized. The scissor valve was added to bleed the pressure off of the mushroom valve. This plumbing of the ventilator circuit allowed a small leakage path back through the flow sensor to the scissor valve exhaust. Although the circuit performed well, the valve has significant shortcomings: it is heavy (250 g.), draws about 600 mA at 12 VDC, and is not rated for continuous operation at 12 VDC. When a PEEP function was implemented with the scissor valve energized longer in the breath duty cycle, the coil overheated. There is no way to reduce the voltage on the coil during operation.

Miniature Air Compressor

The miniature air compressor solved all of the scissor valve problems. It is small, light-weight (131 g.), and draws only 170 mA at 12VDC. It performs adequately by generating 1.2 psi at 3 VDC (using a 2 watt 160 Ohm resistor in series) and draws only 70 mA. This valve also makes PEEP much easier to implement.

The mushroom valve in the ventilator circuit is now energized independent of the main air compressor, see Figure 4. The pressure generated in the tubing to the mushroom valve is bled off through the miniature air compressor when power is turned off, thus allowing the valve to open and the patient to exhale.

Noise

Compressors are noisy. The sound inside the patient circuit was recorded and evaluated: the peak frequency was ~200 Hz with many harmonics. Simple expansion mufflers work by transitioning from a small cross sectional area to a large one and then back to a small one. Mufflers were designed for the main air compressor input and output. They also smooth out the flow from the compressor.

To save space, muffler dimensions would be 3 inches long with a diameter of 2.5 inches. Mufflers with these dimensions were tested in the ventilation circuit and found to significantly reduce compressor noise in the patient circuit. The manifold incorporates these mufflers in a tightly integrated package.

7.4 Single and Dual Compressor Flow Rates

The manifold mufflers were designed to accommodate a second air compressor if more airflow is desired. The inlet and outlet muffler linearly mix and help smooth out the airflows. Note that only a single air compressor is in the current FFLSS prototype.

7.5 Mixing O2 Generator and Single Compressor Flows

The mixer supplied by Scott Aviation mixes the airflow from the compressor and the oxygen generator.

7.6 Subsystem Integration

All subsystems were integrated into a Zero Case for final software development and ventilator testing as shown in the following picture.

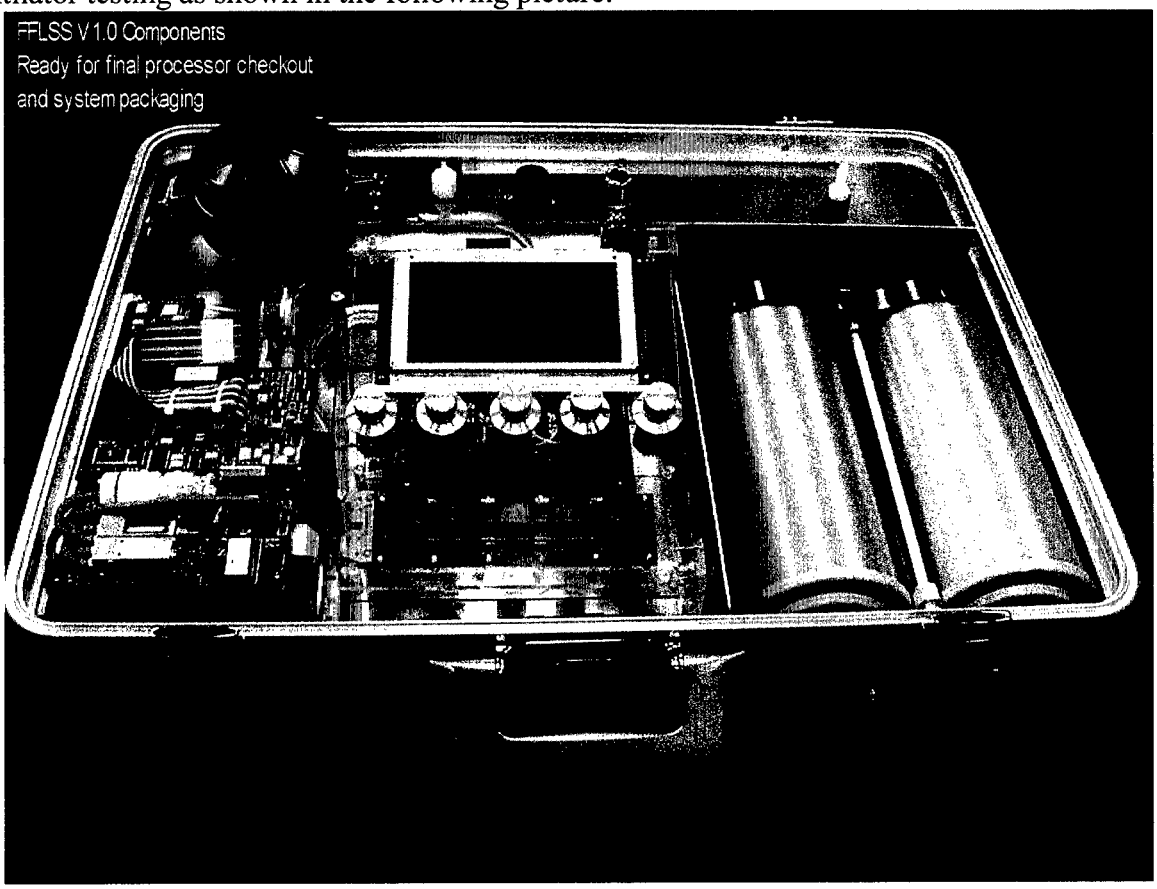

Figure 22 Zero Case FFLSS

7.7 Final Integration

The final prototype case drawings are provided in Section 16.3. All components from the Zero prototype were incorporated into the final version 1.0 prototype. The oxygen generator assembly will remain external to the FFLSS. The actual version 1.0 prototype unit is seen the following picture.

Figure 23 FFLSS Version 1.0 Prototype[e

8 VENTILATOR PERFORMANCE TESTING

8.1 Procedure

At least three of the following variables must be specified to produce a specific ventilator waveform:

- Length of Inspiratory Time or Expiratory Time
- I:E Ratio
- Respiratory Rate
- Tidal Volume
- Minute Volume
- Average Inspiratory Flow.

The following ECRI figure depicts this relationship. Most ventilators have tidal volume, BPM, and peak flow rate set. The remaining variables are then determined from these values.

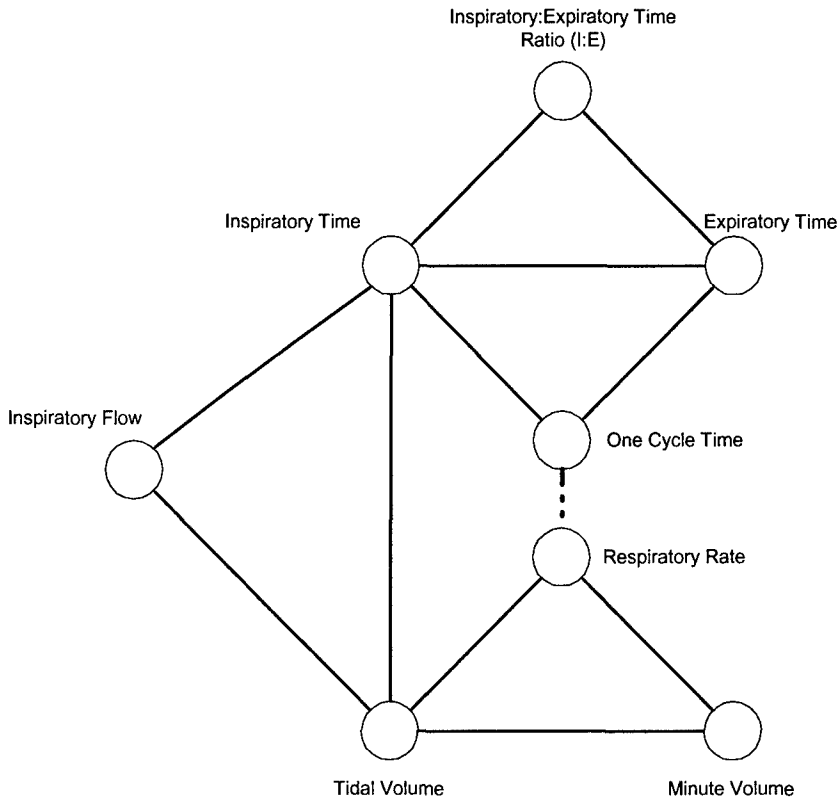

Figure 24 ECRI Relationship between I:E, Flow, Volume, and Frequency Variables

The FFLSS uses a constant flow source, thus inspiratory flow is a constant. Knobs on the front panel can then set tidal volume and BPM. Upon ventilation, minute volume, I:E ratio, actual BPM achieved, and actual tidal volume achieved are measured and displayed.

Ventilator testing includes calibration of BPM, minute volume, tidal volume, and I:E ratio against the test lung. Performance testing is completed across a range of input variables.

8.2 "Zero" FFLSS Results

8.2.1 Calibration

The ventilator prototype was calibrated using the Michigan Instruments test lung. Variables were set on the prototype and then compared to the "gold standard" test lung Pnueview software output. The software was modified to match the test lung, but it should be noted that all calibrations were done with an Allegiance dual adult breathing circuit (approximately 5 feet long) and a resistance of 5 $cmH_2O/L/S$ and a compliance of 0.05 L/cmH_2O. Actual ventilator performance will vary as other breathing circuits and lung parameters are encountered. Up to a ten percent variance between set and delivered parameters is acceptable for adults.

8.2.2 Performance Envelope

Ventilator Zero was used to develop the performance test matrix and the data are shown below. The first two columns are constants set on the test lung by adjusting springs and choosing in-line resistances. Numbers shown in next two columns are set by knobs on the FFLSS. The data in the five center columns (yellow headings) are readings from the FFLSS display. The data shown in the last six columns (gold headings) are from the gold-standard test lung.

Table 1 Ventilator Zero Performance Test Matrix Data-- 0.05/5

Ventilator	Zero			Date	06-Feb-01									
Software Version		1.2		O2 Gen?	no									
Set				Displayed					Test Lung					
Compliance (L/cmH2O)	Resistance (cmH2O/L/S)	Tidal Volume (mL)	Set BPM	Minute Volume (L)	Tidal Volume (mL)	BPM	Max Pressure (cmH2O)	I:E	Minute Volume (L)	Tidal Volume (mL)	Max Pressure (cmH2O)	BPM	Peak Inspiratory Flow (L/S)	I:E
0.05	5	250	10	2.5	270	10	4	1:7.9	2.31	231	3.7	10	22.5	1:5.6
0.05	5	250	15	3.75	270	15	4	1:4.9	3.54	235	3.7	15	22.6	1:3.3
0.05	5	250	20	5	270	20	4	1:3.4	4.6	233	3.8	20	23.6	1:2.2
0.05	5	250	25	4.26	270	19.6	4	1:3.2	4.73	233	3.9	20.1	22.7	1:2.2
0.05	5	250	30	4.87	270	20.1	4	1:3.3	4.61	230	3.9	20.1	23	1:1.9
0.05	5	500	10	5	520	10	7	1:3.4	4.82	482	6.2	10	23.1	1:2.8
0.05	5	500	15	7.15	520	14.1	7	1:2	6.47	480	6.3	14.4	23.2	1:1.7
0.05	5	500	20	7.33	520	14.6	7	1:2	7.05	486	6.3	14.6	23.5	1:1.7
0.05	5	500	25	7.34	520	14.6	7	1:2	7.3	486	6.4	15	23.5	1:1.6
0.05	5	500	30	7.28	520	14.7	7	1:2	7.01	486	6.3	14.5	23.6	1:1.6
0.05	5	750	10	7.5	770	10	9	1:1.9	7.398	740	8.7	10	23.4	1:1.7
0.05	5	750	15	9.03	770	12	9	1:1.4	8.4	735	8.8	12.1	24.1	1:1.3
0.05	5	750	20	9.07	770	12	9	1:1.5	8.9	740	8.7	12	23	1:1.2
0.05	5	750	25	9.18	770	12.1	9	1:1.6	8.8	734	8.8	12.1	25.2	1:1.2
0.05	5	750	30	9.09	770	12.1	9	1:1.7	8.9	736	8.8	12.2	23.9	1:1.2
0.05	5	1000	10	10	1020	10	11	1:1.2	9.98	998	11	10	24	1:1.1
0.05	5	1000	15	10.08	1020	10	12	1:1.1	10.19	993	11.1	10.2	23.7	1:1.1
0.05	5	1000	20	10.32	1020	10.2	12	1:1.2	10.11	992	11.1	10.1	23.8	1:1.1
0.05	5	1000	25	10.24	1020	10.2	12	1:1.3	10.03	988	11.2	10.2	23.7	1:1.1
0.05	5	1000	30	10.34	1020	10	12	1:1.4	10.1	992	11.1	10.2	23.7	1:1.1

Table 2 Ventilator Zero Performance Test Matrix Data-- 0.05/20

Ventilator	Zero			Date	07-Feb-01									
Software Version		1.2		O2 Gen?	no									
Set				Displayed					Test Lung					
Compliance (L/cmH2O)	Resistance (cmH2O/L/S)	Tidal Volume (mL)	Set BPM	Minute Volume (L)	Tidal Volume (mL)	BPM	Max Pressure (cmH2O)	I:E	Minute Volume (L)	Tidal Volume (mL)	Max Pressure (cmH2O)	BPM	Peak Inspiratory Flow (L/S)	I:E
0.05	20	250	10	2.5	280	10	7	1:8.5	2.44	244	6.4	10	24.5	1:5.6
0.05	20	250	15	3.75	280	15	7	1:5.3	3.643	243	6.5	15	24	1:3.3
0.05	20	250	20	4.5	280	18	7	1:4.3	4.404	244	6.5	18	24.3	1:2.4
0.05	20	250	25	4.5	280	18	7	1:4.3	4.341	244	6.4	17.9	24.4	1:2.7
0.05	20	250	30	4.47	280	17.9	7	1:4.3	4.315	242	6.5	17.8	24.5	1:2.8
0.05	20	500	10	5	530	10	9	1:3.8	4.837	485	8.8	10	25	1:3.1
0.05	20	500	15	6.25	530	12.5	9	1:2.9	5.987	479	8.7	12.5	24.8	1:2.3
0.05	20	500	20	6.21	530	12.4	9	1:2.9	6.009	480	8.8	12.4	25.1	1:2.2
0.05	20	500	25	6.28	530	12.5	10	1:2.9	6.005	482	8.9	12.4	25	1:2.2
0.05	20	500	30	6.22	530	12.4	9	1:2.8	5.979	484	8.8	12.4	24.9	1:2.2
0.05	20	750	10	7.5	780	10	11	1:2.2	7.377	738	11.1	10	25.3	1:1.9
0.05	20	750	15	7.53	780	10	12	1:2.2	7.309	730	11.1	10	25.6	1:1.9
0.05	20	750	20	7.53	780	10	12	1:2.2	7.432	726	11.1	10	25.2	1:1.9
0.05	20	750	25	7.53	780	10	12	1:2.2	7.325	735	11.2	10	25.5	1:1.9
0.05	20	750	30	7.53	780	10	12	1:2.2	7.338	734	11	10	25.5	1:1.8
0.05	20	1000	10	8.55	1030	8.5	14	1:1.8	8.333	982	13.4	8.5	25.9	1:1.6
0.05	20	1000	15	8.47	1030	8.4	14	1:1.8	8.42	987	13.3	8.5	26	1:1.6
0.05	20	1000	20	8.53	1030	8.5	14	1:1.8	8.31	986	13.5	8.5	25.4	1:1.6
0.05	20	1000	25	8.52	1030	8.5	14	1:1.8	8.361	982	13.3	8.5	25.6	1:1.6
0.05	20	1000	30	8.51	1030	8.5	14	1:1.8	8.214	986	13.3	8.5	25.5	1:1.7

Table 3 Ventilator Zero Test Matrix Data--0.02/5

Ventilator Zero				Date 07-Feb-01										
Software Version 1.2				O2 Gen? no										
Set				Displayed					Test Lung					
Compliance (L/cmH2O)	Resistance (cmH2O/L/S)	Tidal Volume (mL)	Set BPM	Minute Volume (L)	Tidal Volume (mL)	BPM	Max Pressure (cmH2O)	I:E	Minute Volume (L)	Tidal Volume (mL)	Max Pressure (cmH2O)	BPM	Peak Inspiratory Flow (L/S)	I:E
0.02	5	250	10	2.5	280	10	9	1:8.5	2.54	254	8.2	10	24.1	1:5.8
0.02	5	250	15	3.75	280	15	9	1:5.4	3.82	249	8	15	24.5	1:3.5
0.02	5	250	20	5	280	20	9	1:3.7	5.1	255	8.2	20	24.8	1:2.4
0.02	5	250	25	6.25	280	25	9	1:2.8	6.25	256	8.3	25	24.5	1:1.7
0.02	5	250	30	7.5	280	30	9	1:2.1	7.7	250	8.1	30	24.9	1:1.2
0.02	5	500	10	5	530	10	15	1:3.8	4.9	489	14	10	25.1	1:3.1
0.02	5	500	15	7.5	530	15	15	1:2.2	7.4	493	14	15	24.5	1:1.8
0.02	5	500	20	10	530	20	15	1:1.4	9.92	493	14	20	25.5	1:1.1
0.02	5	500	25	12.14	530	24.2	15	1:1	11.84	489	14.1	24.3	24.8	1:.6
0.02	5	500	30	12.14	520	24.2	15	1:1	11.8	489	14.1	24.3	24.6	1:.6
0.02	5	750	10	7.5	770	10	21	1:2.2	7.36	736	19.8	10	24.8	1:2
0.02	5	750	15	11.25	770	15	21	1:1.1	12	740	19.9	15	26.7	1:1
0.02	5	750	20	14.06	770	18.7	21	1:.7	13.89	741	20	18.4	24.7	1:.5
0.02	5	750	25	13.95	770	18.4	21	1:.7	13.5	738	20	18.4	24.8	1:.5
0.02	5	750	30	13.88	770	18.5	21	1:.7	13.82	738	20	18.8	25.1	1:.5
0.02	5	1000	10	10	1020	10	27	1:1.4	9.8	980	25.6	10	25	1:1.3
0.02	5	1000	15	15	1020	15	27	1:.6	14.77	986	25.8	15	26.3	1:.5
0.02	5	1000	20	15.42	1020	15.4	27	1:.5	14.97	983	25.7	15.2	26.3	1:.5
0.02	5	1000	25	15.34	1020	15.3	27	1:.5	15.09	984	25.8	15.3	25.6	1:.4
0.02	5	1000	30	15.3	1020	15.2	27	1:.5	14.99	988	25.9	15.3	25.9	1:.4

Table 4 Ventilator Zero Performance Test Matrix Data-- 0.02/20

Ventilator Zero				Date 07-Feb-01										
Software Version 1.2				O2 Gen? no										
Set				Displayed					Test Lung					
Compliance (L/cmH2O)	Resistance (cmH2O/L/S)	Tidal Volume (mL)	Set BPM	Minute Volume (L)	Tidal Volume (mL)	BPM	Max Pressure (cmH2O)	I:E	Minute Volume (L)	Tidal Volume (mL)	Max Pressure (cmH2O)	BPM	Peak Inspiratory Flow (L/S)	I:E
0.02	20	250	10	2.5	280	10	10	1:8.5	2.528	253	10	10	24.5	1:5.6
0.02	20	250	15	3.75	280	15	10	1:5.5	3.772	252	10.2	15	24.2	1:3.5
0.02	20	250	20	5	280	20	10	1:3.7	5.11	255	10.2	20	24.9	1:2.3
0.02	20	250	25	6.25	280	25	10	1:2.8	6.359	255	10.2	25	24.4	1:1.7
0.02	20	250	30	7.5	280	30	10	1:2.2	7.686	257	10.3	29.6	24.5	1:1.4
0.02	20	500	10	5	530	10	16	1:3.8	4.908	492	5.9	10	24.4	1:3.1
0.02	20	500	15	7.5	520	15	16	1:2.2	7.381	493	16	15	24	1:1.8
0.02	20	500	20	10	520	20	16	1:1.4	9.922	494	16	20	24.4	1:1.1
0.02	20	500	25	10	530	20	16	1:1.4	9.826	496	16.1	20	24.4	1:1.1
0.02	20	500	30	10.03	520	20	16	1:1.4	9.992	495	16.2	20	24.4	1:1.1
0.02	20	750	10	7.5	770	10	23	1:2.2	7.37	738	21.8	10	24.7	1:2
0.02	20	750	15	11.25	770	15	23	1:1.1	11.144	745	21.7	15	25.1	1:1
0.02	20	750	20	11.27	770	15	23	1:1.1	11.176	743	21.9	15	25.9	1:1
0.02	20	750	25	11.27	770	15	23	1:1.1	11.112	741	21.9	15	25.5	1:1
0.02	20	750	30	11.27	770	15	23	1:1.1	11.084	743	21.8	15	25	1:1
0.02	20	1000	10	10	1020	10	29	1:1.4	9.814	981	27.4	10	24.5	1:1.3
0.02	20	1000	15	12.39	1020	12.4	28	1:.9	12.2	989	27.5	12.4	25.3	1:.8
0.02	20	1000	20	12.39	1020	12.4	28	1:.9	12.116	986	27.6	12.3	25.2	1:.8
0.02	20	1000	25	12.44	1020	12.4	28	1:.9	12.12	987	27.5	12.3	25.1	1:.8
0.02	20	1000	30	12.42	1020	12.4	28	1:.9	12.164	985	27.7	12.3	25	1:.8

The data in these four tables looks very reasonable, and understandable. The inspiratory time is always determined from the tidal volume chosen. When I:E reached ~1:1, faster rates cannot be achieved, and minute ventilation does not increase further.

To explore the limits of minute volume achievable versus BPM and tidal volume delivered, the data are plotted to show the ventilator's maximum operating limits for each of the four loads studied. Consider the four Normal Load (C .05 R 5) points. The machine can deliver any tidal volume/frequency combination to the left of or below those points, but cannot achieve any point above or to the right of the line connecting those points. For reference, three lines of constant minute ventilation (8, 10 and 12 l/min) have been superimposed over the measured data. Clearly, ventilator is limited to less than 10 l/min (without O_2 generators), depending on the frequency or tidal volume chosen.

The situation is a lot better for the low compliance case, and somewhat better than normal even if high resistance occurs in the low compliance case. High resistance alone further compromises the machine's ability to deliver gas.

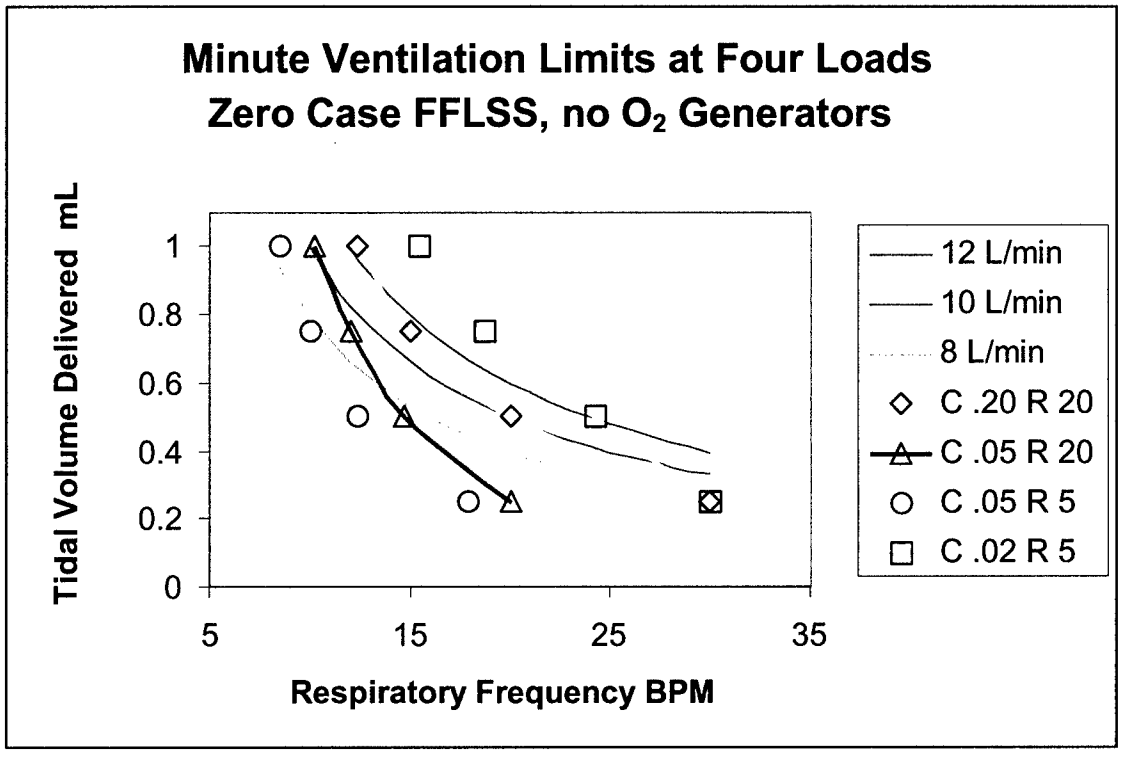

Figure 25 Minute Ventilation Limits at Four Loads Zero Case FFLSS, No O_2 Generators, Exhalation Valve Positive Pressure Only

8.3 FFLSS Version 1.0 Prototype Performance

The same calibration and tests were run on the version 1.0 final prototype unit. Here, the recording of test data was stopped once the maximum minute volume was attained.

Table 5 Ventilator 1.0 Prototype Performance Test Matrix Data-- 0.05/5

Ventilator	Unit 1			Date	21-Mar-01		Voltage	13.1						
Software Version		1.4		O2 Gen?	no									
Set				Displayed					Test Lung					
Compliance (L/cmH2O)	Resistance (cmH2O/L/S)	Tidal Volume (mL)	Set BPM	Minute Volume (L)	Tidal Volume (mL)	BPM	Max Pressure (cmH2O)	I:E	Minute Volume (L)	Tidal Volume (mL)	Max Pressure (cmH2O)	BPM	Peak Inspiratory Flow (L/S)	I:E
0.05	5	250	10	2.5	250	10	4	1:6.5	2.54	252	4.3	10	21.8	1:5.6
0.05	5	250	15	3.75	250	15	4	1:4.1	3.82	254	4.2	15	21.7	1:3.4
0.05	5	250	20	5	250	20	4	1:2.8	5.09	254	4.2	20	21.4	1:2.4
0.05	5	250	25	6.25	250	25	4	1:2.1	6.18	241	4.2	25	20.5	1:1.7
0.05	5	250	30	7.5	250	30	4	1:1.5	7.63	241	4.2	30	20	1:1.4
0.05	5	500	10	5	500	10	6	1:3	4.99	497	6.5	10	22	1:2.8
0.05	5	500	15	7.5	500	15	6	1:1.7	7.48	495	6.5	15	22	1:1.5
0.05	5	500	20	10	500	20	6	1:1	9.97	499	6.5	20	21.2	1:.4
0.05	5	500	25	11.53	500	23	6	1:.7	11.47	490	6.5	23	21.7	1:.5
0.05	5	500	30											
0.05	5	750	10	7.5	750	10	9	1:1.7	7.51	751	8.9	10	21.5	1:1.6
0.05	5	750	15	11.25	750	15	9	1:.8	11.2	746	8.8	15	22.6	1:.5
0.05	5	750	20	12.78	750	17.3	9	1:.6	12.87	752	8.9	17	22.5	1:.6
0.05	5	750	25											
0.05	5	750	30											
0.05	5	1000	10	10	1000	10	11	1:1	10.1	1004	11.1	10	22.8	1:1
0.05	5	1000	15	13	1000	13.1	11	1:.6	13.14	1008	11.1	13	22.9	1:.4
0.05	5	1000	20											
0.05	5	1000	25											
0.05	5	1000	30											

Table 6 Ventilator 1.0 Prototype Performance Test Matrix Data-- 0.02/5

Ventilator	Zero			Date	7-Feb-01									
Software Version		1.2		O2 Gen?	no									
Set				Displayed					Test Lung					
Compliance (L/cmH2O)	Resistance (cmH2O/L/S)	Tidal Volume (mL)	Set BPM	Minute Volume (L)	Tidal Volume (mL)	BPM	Max Pressure (cmH2O)	I:E	Minute Volume (L)	Tidal Volume (mL)	Max Pressure (cmH2O)	BPM	Peak Inspiratory Flow (L/S)	I:E
0.02	5	250	10	2.5	250	10	8	1:6.5	2.653	264	8.5	10	22.8	1:5.5
0.02	5	250	15	3.75	250	15	8	1:4.1	3.937	263	8.5	15	21.7	1:3.4
0.02	5	250	20	5	250	20	8	1:2.7	5.28	262	8.5	20.1	22.7	1:2.3
0.02	5	250	25	6.25	250	25	8	1:2	6.697	267	8.5	25	21.9	1:1.6
0.02	5	250	30	7.5	250	30	8	1:1.5	7.818	265	8.5	30.2	21.3	1:1
0.02	5	500	10	5	500	10	14	1:3	5.146	512	14.5	10	21.7	1:2.7
0.02	5	500	15	7.5	500	15	14	1:1.7	7.663	514	14.5	15.2	22.6	1:1.5
0.02	5	500	20	10	500	20	14	1:1	10.33	513	14.5	20	21.6	1:.9
0.02	5	500	25	12	500	24	14	1:1.6	12.395	515	14.5	24.1	22.9	1:.3
0.02	5	500	30											
0.02	5	750	10	7.5	750	10	20	1:1.7	7.639	766	20.3	10	22.8	1:1.6
0.02	5	750	15	11.25	750	15	20	1:.8	11.471	76	20.4	15.1	21.4	1:.7
0.02	5	750	20	13.51	750	18.1	20	1:.5	13.791	765	20.5	18.1	21.8	1:.3
0.02	5	750	25											
0.02	5	750	30											
0.02	5	1000	10	10	1000	10	26	1:1	10.656	1002	26.1	10	21.4	1:1
0.02	5	1000	15	14	1000	14.1	26	1:.4	14.13	1004	26.2	14.1	22.2	1:.2
0.02	5	1000	20											
0.02	5	1000	25											
0.02	5	1000	30											

Table 7 Ventilator 1.0 Prototype Performance Test Matrix Data-- 0.05/20

Ventilator Software Version	Zero	1.2		Date O2 Gen?	7-Feb-01 no									
Set				Displayed					Test Lung					
Compliance (L/cmH2O)	Resistance (cmH2O/L/S)	Tidal Volume (mL)	Set BPM	Minute Volume (L)	Tidal Volume (mL)	BPM	Max Pressure (cmH2O)	I:E	Minute Volume (L)	Tidal Volume (mL)	Max Pressure (cmH2O)	BPM	Peak Inspiratory Flow (L/S)	I:E
0.05	20	250	10	2.5	250	10	6	1:6.5	2.457	247	4.1	10	21.1	1:5.4
0.05	20	250	15	3.75	250	15	6	1:4	3.642	242	4.1	15	22.5	1:3.3
0.05	20	250	20	5	250	20	6	1:2.7	4.904	244	4.1	20	21.1	1:2.3
0.05	20	250	25	6.25	250	25	6	1:2	5.952	236	4.1	25	21.8	1:8
0.05	20	250	30	7.5	250	30	6	1:1.5	7.533	251	4.2	30.3	21	1:1.1
0.05	20	500	10	5	500	10	8	1:3	4.883	496	6.5	10	21.3	1:2.7
0.05	20	500	15	7.5	500	15	8	1:1.6	7.346	489	6.5	15	21.5	1:1.5
0.05	20	500	20	9	500	18.1	8	1:1.2	8.836	487	6.4	18.1	229	1:1
0.05	20	500	25											
0.05	20	500	30											
0.05	20	750	10	7.5	750	10	10	1:1.7	7.399	738	8.8	10.1	22.4	1:1.6
0.05	20	750	15	9.76	750	13.1	10	1:1	9.652	738	8.8	13	22.3	1:.8
0.05	20	750	20											
0.05	20	750	25											
0.05	20	750	30											
0.05	20	1000	10	10	1000	10	12	1:1	9.943	988	11	10	21.9	1:1
0.05	20	1000	15	11	1000	11.1	12	1:.8	10.921	992	11.2	11	22	1:.8
0.05	20	1000	20											
0.05	20	1000	25											
0.05	20	1000	30											

Table 8 Ventilator 1.0 Prototype Performance Test Matrix Data-- 0.02/20

Ventilator Software Version	Zero	1.2		Date O2 Gen?	7-Feb-01 no									
Set				Displayed					Test Lung					
Compliance (L/cmH2O)	Resistance (cmH2O/L/S)	Tidal Volume (mL)	Set BPM	Minute Volume (L)	Tidal Volume (mL)	BPM	Max Pressure (cmH2O)	I:E	Minute Volume (L)	Tidal Volume (mL)	Max Pressure (cmH2O)	BPM	Peak Inspiratory Flow (L/S)	I:E
0.02	20	250	10	2.5	250	10	9	1:6.6	2.578	253	8.5	10	21.2	1:5.6
0.02	20	250	15	3.75	250	15	9	1:4.1	3.832	254	8.5	15	20.9	1:3.4
0.02	20	250	20	5	250	20	9	1:2.8	5.098	255	8.5	20	21.1	1:2.2
0.02	20	250	25	6.25	250	25	9	1:2	6.414	255	8.5	25	21	1:1.6
0.02	20	250	30	7.5	250	30	9	1:1.5	7.419	247	8.5	30	21.3	1:.6
0.02	20	500	10	5	500	10	15	1:5	4.982	495	14.5	10	21.2	1:2.7
0.02	20	500	15	7.5	500	15	15	1:1.6	7.461	495	14.4	15	21.8	1:1.5
0.02	20	500	20	10	500	20	15	1:1	10.034	498	14.5	20.3	20.8	1:.6
0.02	20	500	25	10.86	500	21.4	15	1:.8	11.243	538	20.8	21	21.1	1:.6
0.02	20	500	30											
0.02	20	750	10	7.5	750	10	15	1:1.7	7.291	736	20	10	21.2	1:1.6
0.02	20	750	15	11.25	750	15	15	1:.8	11.197	738	20.1	15	20.7	1:.6
0.02	20	750	20	11.74	750	15.2	21	1:.7	12.145	773	25.7	15.7	22.1	1:.6
0.02	20	750	25											
0.02	20	750	30											
0.02	20	1000	10	10	1000	10	20	1:1	9.783	975	25.7	10	22.1	1:1
0.02	20	1000	15	13.39	1000	13.9	26	1:.5	13.622	1012	31.5	13.5	21.1	1:.6
0.02	20	1000	20											
0.02	20	1000	25											
0.02	20	1000	30											

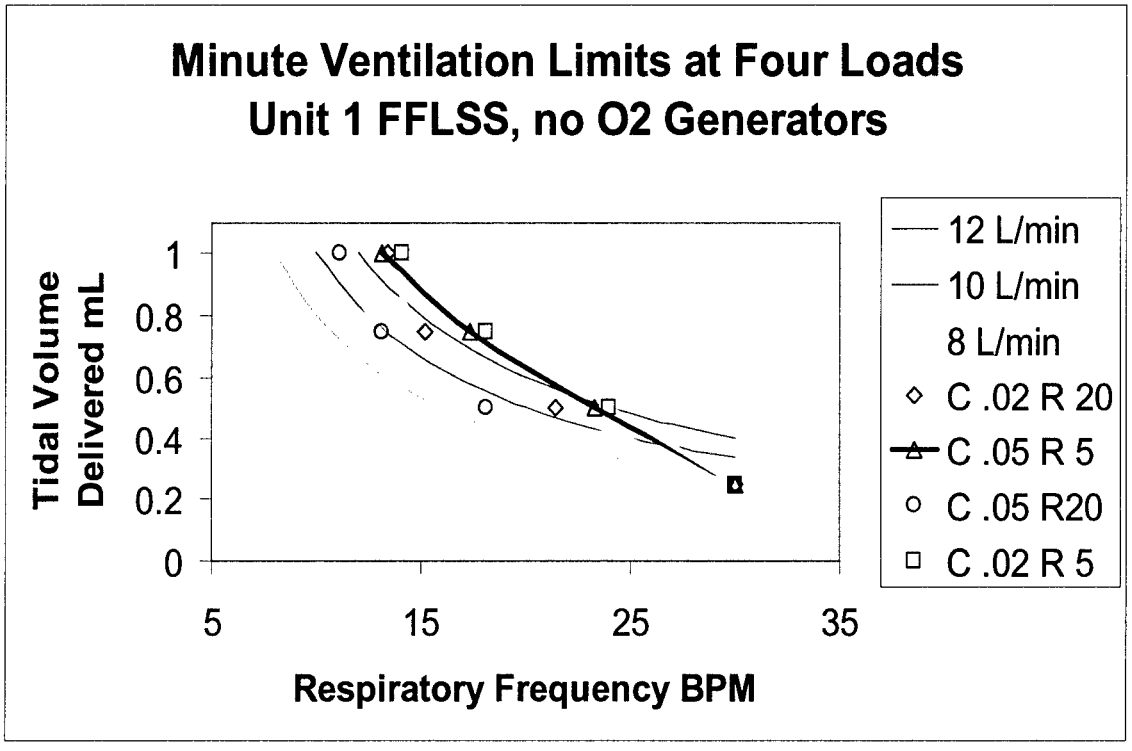

Figure 26 Minute Ventilation Limits at Four Loads Zero Case FFLSS, No O_2 Generators, Exhalation Valve Positive and Negative Pressure

The FFLSS 1.0 prototype used a miniature air compressor to open the pneumatic exhalation valve faster and more fully. As seen in the above Figures, performance was enhanced and all curves moved to the right. Under nominal conditions of compliance of 0.05 and resistance of 5, green curve, the minute ventilation delivered by the ventilator was at or above 12 L/min. When the resistance was increased to an R of 20, the minute ventilation was reduced, but in all cases remained above 8 L/min (circle and diamond curves).

8.4 ECRI Testing

Independent testing was performed at the Emergency Care Research Institute in Plymouth Meeting, PA. The goal was to have their qualified personnel treat this prototype as they would any commercial ventilator that was sent to them for testing.

JHU/APL Personnel:	Dr. Dexter Smith and Terrie Denney
Facility:	ECRI, Plymouth Meeting, PA
Dates:	April 8-10 2001
Purpose of Trip:	Demonstrate FFLSS Ventilator Mechanical and Software Operations and Battery Life Under Full FFLSS Operations

8.4.1 ECRI Written Comments

01/10/01 4:28pm 469662.WGE Page 1: This document contains the preliminary findings of ECRI's testing of the Far Forward Life Support Systems ventilation performance. APL is currently designing these units.

The unit ventilates at a constant flow of approximately 16 liters per minute. At the time of testing, the unit has continuous mandatory ventilation mode (CMV) with user adjustable tidal volume, respiratory rate (limited by flow and tidal volume) and a pressure-limiting device. It is also equipped with an alarms package, pressure monitoring and volume monitoring.

We tested the unit by connecting the breathing circuit to a Michigan Instruments Vent-Aid TTL test lung set for varying compliances with a parabolic flow resistor in line. We measured pressure, flow, and volume at the wye connector with a ventilator tester developed at ECRI. We tested the units performance throughout the range of tidal volumes of 300 mL to the maximum of 2000 mL, respiratory rates of 6 to a maximum of 20 breathes per minute and pressure limited from 20 to 60 cmH2O. All performance testing was done with the unit operating on battery power at 12.3 Volts. The unit also operated with supplemental oxygen of 2 lpm.

All performance specifications were within 10% of all settings and alarms and safety features functioned properly. Some of the settings resulted in inverse ratio ventilation: while this type of ventilation would be avoided in some patient populations (e.g. chronic obstructive pulmonary disease) it may be helpful to the trauma patient. This should be explored further with clinicians. APL should further explore the need for a cautionary warning when inverse ratio ventilation parameters are set.

01/10/01 4:28pm 469662.WGE Page 2: Recommendations
(√ indicates change made following ECRI testing)

Alarms and Monitors

- Continuous display of message indicating that the audible alarm is disabled. √
- An alarm silence feature that will temporarily silence the alarm (e.g. 120 sec). √

- Audible alarm automatically cancels if alarm situation is remedied. A visual alarm will remain until reset.
- Include a continuous sounding alarm for ventilator system failure.
- Include a low battery alarm (e.g. 30 mts. of battery power remaining) and a prolonged inspiratory period alarm. √
- Minute volume calculated on a rolling average. √

Unit Design

- Settings confirmation button for setting changes √
- Protective covering for tubing connections
- Power switch protected √
- Relocated suctioning switch √
- Protective cover for exhalation port

8.4.2 ECRI Recommendations

(√ indicates change made following ECRI testing)

1. Add *System Failure* alarm (a unique, constant sound) with solid red text display
2. Add *Exhale Circuit Blocked* alarm √
3. Add *Immediate Silence* Button for audible alarms √
4. Add *Audible Alarm Disabled* Text to Display √
5. Add *Auto-Alarm Restart* Feature for alarm conditions that are not resolved within ~2 minutes of activating *Immediate Silence* √ 60 secs
6. Add CO_2 *Off* indicator
7. Add *BPM Off* indicator
8. Add *Accept Change* Button to initiate manual/software settings √
9. Start-up Display should be Red/Red/Flash with text words *Ventilator Not Running* √
10. Modify display to handle text explanation for cleared alarms (i.e. how resolved)
11. Consider timer for Oxygen generator with an audible alert for low oxygen
12. Label all switches and knobs
13. Add single-slide cover to protect external connection points (from clogging materials)
14. On Display, label vertical axis as "Units"

8.4.3 ECRI Test 1: FFLSS Ventilator Mechanical and Software Operations 9 Apr 01

ECRI and JHU/APL set up ventilator and tested each component to ensure system operates according to design specifications. Battery voltage: 12.3 (actual) vs 11.7 (on display)

Suction: Obtained 390 millimeters mercury at end of the 6ft Tygon tube R-3603 (3/8")
Even at full stop did not exceed 400.
ECRI Notes: FYI: danger zone at ~500 and never exceed 600 (will kill tissue)

Ventilation: Set T Vol 1000 BPM 25 Delivers 905 Set T Vol 1000 BPM 15 Delivers 909
Some Tidal Volume lost in tube: Variances of 10% acceptable range

Changed ECRI Lung to 0.05 compliance to correspond with pre-test calibration
Result: At T Vol 1000 BPM 25 Delivers 990 mL

Exhale Circuit: No alarm for bocked exhalation: system waits for next breath (it won't come if patient is not breathing.) Other data calculations based upon *previous breath* so alarm is needed. Ventilator was turned off during inhalation, and the exhalation "pop" valve opened as required.
Explore single-limb vs dual limb circuit

Overpressure: Alarm sounded as required.

System Failure: No alarm: Must remedy.

Minute Volume: Set to be a running average, usually 6-7 breaths

Tidal Volume: When changed from 500 to 0 to 300, alarm sounded

Alarms: Should have a button to silence audible alarms for approximately 2 minutes. When silenced or disabled, there should be a text note on the display that reads "ALARM DISABLED", and text area for alarm remedies.

Oxygen Generators: Used O_2 Canister 1 (Time: 1315-1343) [T Vol= Tidal Volume)

T Vol 700	BPM 15 Flow 2 lpm	
T Vol 750	BPM 17.3 Flow 2.3 lpm	Min Vol 13.63 Pmax 39
Pull off oxygen	BPM not received then 15	Min Vol 11.25

Turned off ventilator: exhalation valve opened vented off T Vol counting
Restart failed: powered down to restart connected O_2 : T Vol 2000

T Vol 1000	BPM 12	Min Vol 12.96
T Vol 1000	BPM set for 15, giving 13	Min Vol 13.9
T Vol 500	BPM 23.3	Min Vol 12.69

(Oxygen off Flow 2.3 Min Vol was 11.7)

O_2 Monitor: Used O_2 Canister 2 (Time: 1343-1406)

@ 700-800	BPM 12	Pulse Ox on
T Vol 700	BPM 15	O2 @ 34.9%
T Vol 500	BPM 15	O2 @ 44.0%
T Vol 1000	BPM 10	O2 @ 37.0%

O2 Average of 40% appeared to be independent of T Vol
Moved O_2 Monitor to Vent area: Raised baseline of %, increased flow: Could not measure due to wash over. Each O_2 Canister raised flow only 2Lpm.

Breathing Circuit: Did not kink, but can disconnect from ventilator: should get alarm.
BP disconnect delivered message *BPM Not Reached*, but no audible.

Exhalation disconnect triggered alarm after 3 breaths. Clear air should "see 26/27". O_2 pressure sensor sounded alarm and displayed strange text. supposed vent off. Mechanical Pop Valve functioned.

CO_2 : No mechanical way to test; no alarm or display notification that CO_2 is off.

SIMV: Not In Service

PEEP: Not In Service

Default Settings: In alarm when turned on (due to no CO_2)
Level 1: All came on Red: Ventilator Off, Ventilation Running, Alarm Should be red/red/flashing
Level 2: Retained Reds from Level 1—should have "own" colors
Level 3: Retained Reds from Level 1—should have "own" colors

I:E: Measured and found acceptable.

Fixed Pressure Relief: Reset to 60-65 cmH2O. 40 cmH2O is too low.

8.4.4 Test 2: Battery Life Under Full FFLSS Operations 10 April 2001

ECRI and JHU/APL personnel tested the Army BA-5590/U battery under FFLSS full operations. Blood pressure was initiated every 5 minutes and suction was initiated for 30 seconds every five minutes to stress the ventilator. Airway resistance was 20 cmH2O/L/S and compliance was 0.020 L/cmH2O.

Table 9 Chronology of Battery Life Test: FFLSS Full Operations

BATTERY HOUR	TIME	BP AND SUCTION ON	BP AND SUCTION OFF	COMMENTS
1	0739			Start Stop for Battery Check Test Meter Reading: 14.5/14.5V Ventilator Display: 12.3V
	0740			Start Test Settings: 50cm max Water Pressure High Tidal-1000 BPM- 12 Min Vol- 12.0 lpm I/E- 1:6
		0747.0	0747.30	
		0752.0	0752.30	
		0757.0	0757.30	Side Remark: Vents take up to 38 sec to start-how fast is this on average?
		0802.01	0802.33	
		0807.01	0807.33	
		0812.03	0812.33	
		0817.02	0817.32	
		0822.05	0822.35	
		0827.01	0827.31	
		0832.02	0832.36	
		0837.02	0837.32	
		0842.01	0842.31	
2	0847	0847.01	0847.31	
		0852.03	0852.33	
		0857.01	0857.52	
		0902.04	0902.39	
		0907.00	0907.30	Rate back up to 12
		0912.00	0912.30	
		0917.02	0917.32	
		0922.00	0922.35	
		0927.00	0927.30	
		0932.02	0932.32	HR default SP02 for BP
		0937.05	0937.35	

BATTERY HOUR	TIME	BP AND SUCTION ON	BP AND SUCTION OFF	COMMENTS
		0942.00	0942.33	
3	0947	0947.00	0947.30	40% O_2 when generated, or measured at, patient connection
		0952.00	0952.30	
		0957.00	0957.32	
		1002.00	1002.30	
		1007.00	1007.30	Temp inside is desired
		1012.39	1013.09	
		1017.04	1017.44	
		1022.00	1022.30	
		1027.00	1027.30	
		1032.00	1032.30	
		1037.00	1037.30	OP and Store temp should be 14-122F
		1042.02	1042.32	
4	1047	1047.00	1047.31	
		1052.00	1052.30	
		1057.00	1057.30	
		1102.00	1102.30	
		1107.00	1107.30	
		1112.03	1112.33	
		1117.00	1117.30	
		1122.00	1122.30	
		1127.00	1127.30	
		1132.00	1132.30	
		1137.00	1137.30	13.3V→12.8V on display
		1142.00	1142.34	
5	1147	1147.00	1147.30	
		1152.00	1152.30	
		1157.00	1157.30	Suction heating noise w/compressor sounds different
		1202.00	1202.30	
		1207.00	1207.30	
		1212.00	1212.30	
		1217.00	1217.30	Ventilator switched off: back on at 1217.34
		1222.00	1222.31	
		1227.00	1227.31	
		1232.00	1232.32	
		1237.00	1237.30	
		1242.00	1242.30	
6	1247	1247.00	1247.30	
		1252.00	1252.30	

BATTERY HOUR	TIME	BP AND SUCTION ON	BP AND SUCTION OFF	COMMENTS
		1257.00	1257.30	
		1302.00	1302.30	
		1307.00	1307.30	13.1V→12.7V on display
		1312.00	1312.30	
		1317.00	1317.30	
		1322.00	1322.30	
		1327.00	1327.30	
		1332.00	1332.30	
		1337.00	1337.30	
		1342.00	1342.30	
7	1347	1347.00	1347.30	
		1352.00	1352.30	
		1357.00	1357.30	
		1402.00	1402.30	
		1407.00	1407.30	
		1412.00	1412.30	
		1417.00	1417.30	
		1422.00	1422.31	Power Cycled
		1427.00	1427.30	
		1432.00	1432.30	
		1437.00	1437.30	
		1442.00	1442.30	
8	1447	1447.00	1447.30	
		1452.00	1452.30	
		1457.00	1457.30	13.1V→12.5V on display same as earlier
		1502.00	1502.30	
		1507.00	1507.30	
		1512.00	1512.30	
		1517.00	1517.30	
		1522.00	1522.30	
		1527.00	1527.30	Inverse I:E warning
		1532.00	1532.30	
		1537.00	1537.30	
		1542.00	1542.30	13.0-12.4 with no suction ///12.1 with suction
9	1547	1547.00	1547.30	
		1552.00	1552.30	
		1557.00	1557.30	Inverse I:E helps trauma?
		1602.00	1602.30	11.8 with no suction/// 12.0 with suction
		1607.00	1607.30	
		1612.00	1612.30	
		1617.00	1617.30	12.8 – 12.1 no suction to suction on voltage

BATTERY HOUR	TIME	BP AND SUCTION ON	BP AND SUCTION OFF	COMMENTS
		1622.00	1622.30	12.8-12.0 with no suction///11.6 with suction
		1627.00	1627.30	I:E =1:4
		1632.00	1632.30	
		1637.00	1637.30	Battery Low Alarms
		1642.00	1642.30	11.1 with suction
		1647.00	1647.30	10.8 with suction
		1652.00	1652.30	10.2 with suction BPM not reached
		1653.00		I:E= 1:3 12.1-10.9 with no suction
		1656.00		3.7 sec I (was 2.4)
10	1657	1657.00	1657.30	BPM not reached 9.9 with suction
		1658.00		BPM 1.7
			1658.30	BPM 10.0 I/E=1:4
		1659.19		11.7 – 10.4 with no suction
	1702.08			Compressor died or electronics
	1704.00			11.1 - 9.6
		1707.00	1707.30	7.9 with suction 9.6 BPM
	1709.49			I;E=1:3 9.0 BPM
	1710.34			I:E= 1:2 9.4 V min
	1711.40			Display Off
	1712.02			Battery Dead: Ventilator Off

8.5 Final Army Prototype Testing

Following the testing at ECRI a number of minor modifications were made to the FFLSS prototype. Some addressed ECRI observations as noted above. Others were implemented to make the unit more rugged internally - lock washers on all nuts, Lock-tight where appropriate. One final modification involved the mechanical exhalation valve. A single commercial one was procured during Phase I. This valve was adjustable from close to zero to over 110 cmH2O. Partially based on ECRI inputs, we decided to replace the one of a kind adjustable valve with a commercial pop off valve set to 106 cmH2O (note that the company can produce any pressure desired). This valve necessitated changes in the internal plumbing, i.e. more elbows and an additional T. This additional resistance resulted in a slight degradation in performance as seen in Tables 8 and 9 below.

Table 10 Army Prototype Performance Test Matrix Data-- 0.05/5

Ventilator	Army Ventilator			Final Test			Voltage	13.1							
Software Version		1.5		O2 Gen	no										
Set				Displayed					Test Lung						
Compliance (L/cmH2O)	Resistance (cmH2O/L/S)	Tidal Volume (mL)	Set BPM	Minute Volume (L)	Tidal Volume (mL)	BPM	Max Pressure (cmH2O)	I:E	Minute Volume (L)	Tidal Volume (mL)	Max Pressure (cmH2O)	BPM	Peak Inspiratory Flow (L/S)	I:E
0.05	5	250	10	2.5	250	10	4	1:5.4	2.482	0.248	3.7	10	18.3	1:4.6
0.05	5	250	15	3.75	250	15	4	1:3.3	3.69	0.249	3.7	15	18.5	1:2.7
0.05	5	250	20	5	250	20	4	1:2.2	4.964	0.248	3.7	20	18.5	1:1.7
0.05	5	250	25	6.25	250	25	4	1:1.5	6.105	0.244	3.7	25	18.4	1:1.2
0.05	5	250	30	7.5	250	30	4	1:1	7.317	0.239	3.7	30	18.4	1:.4
0.05	5	500	10	5	500	10	6	1:2.4	4.922	0.492	6.1	10	18.7	1:2.2
0.05	5	500	15	7.5	500	15	6	1:1.2	7.396	0.494	6.1	15	18.8	1:1.1
0.05	5	500	20	10	500	20	6	1:.7	9.834	0.492	6.1	20	18.2	1:.4
0.05	5	500	25											
0.05	5	500	30											
0.05	5	750	10	7.5	750	10	8	1:1.3	7.472	0.746	8.5	10	19.1	1:1.2
0.05	5	750	15	11.25	750	15	9	1:.5	11.12	0.739	8.5	15	19.2	1:.4
0.05	5	750	20											
0.05	5	750	25											
0.05	5	750	30											
0.05	5	1000	10	10	1000	10	11	1:.7	10.023	1.002	10.9	10	19.5	1:.7
0.05	5	1000	15	12	1000	12	11	1:.4	11.915	0.995	10.8	12	19.4	1:.4
0.05	5	1000	20											
0.05	5	1000	25											
0.05	5	1000	30											

Table 11 Army Prototype Performance Test Matrix Data-- 0.05/20

Ventilator	Army Ventilator			Final Test			Volts	13.1						
Software Version		1.5		O2 Gen	no									
Set				Displayed					Test Lung					
Compliance (L/cmH2O)	Resistance (cmH2O/L/S)	Tidal Volume (mL)	Set BPM	Minute Volume (L)	Tidal Volume (mL)	BPM	Max Pressure (cmH2O)	I:E	Minute Volume (L)	Tidal Volume (mL)	Max Pressure (cmH2O)	BPM	Peak Inspiratory Flow (L/S)	I:E
0.05	20	250	10	2.5	250	10	5	1:5.4	2.444	0.245	3.9	10	17.8	1:4.5
0.05	20	250	15	3.75	250	15	5	1:3.3	3.688	0.247	3.9	15	18.2	1:2.7
0.05	20	250	20	5	250	20	5	1:2.2	4.89	0.236	3.9	20	18.4	1:1.8
0.05	20	250	25	6.25	250	25	5	1:1.5	5.93	0.237	3.9	25	18.8	1:.8
0.05	20	250	30	6.75	250	27.1	5	1:1.3	6.662	0.247	3.9	27	18.4	1:.9
0.05	20	500	10	5	500	10	7	1:2.4	4.957	0.496	6.3	10	18.6	1:2.2
0.05	20	500	15	7.5	500	15	7	1:1.2	7.369	0.492	6.3	15	18.5	1:.7
0.05	20	500	20	8.52	500	17.3	7	1:1	8.364	0.493	6.4	17.2	19.2	1:.7
0.05	20	500	25											
0.05	20	500	30											
0.05	20	750	10	7.5	750	10	10	1:1.3	7.472	0.747	8.7	10	19.3	1:1.2
0.05	20	750	15	9	750	12	10	1:.9	9.001	0.753	8.7	12	19.1	1:.7
0.05	20	750	20											
0.05	20	750	25											
0.05	20	750	30											
0.05	20	1000	10	10	1000	10	12	1:.7	10.025	1.004	11.1	10	19.6	1:.7
0.05	20	1000	15											
0.05	20	1000	20											
0.05	20	1000	25											
0.05	20	1000	30											

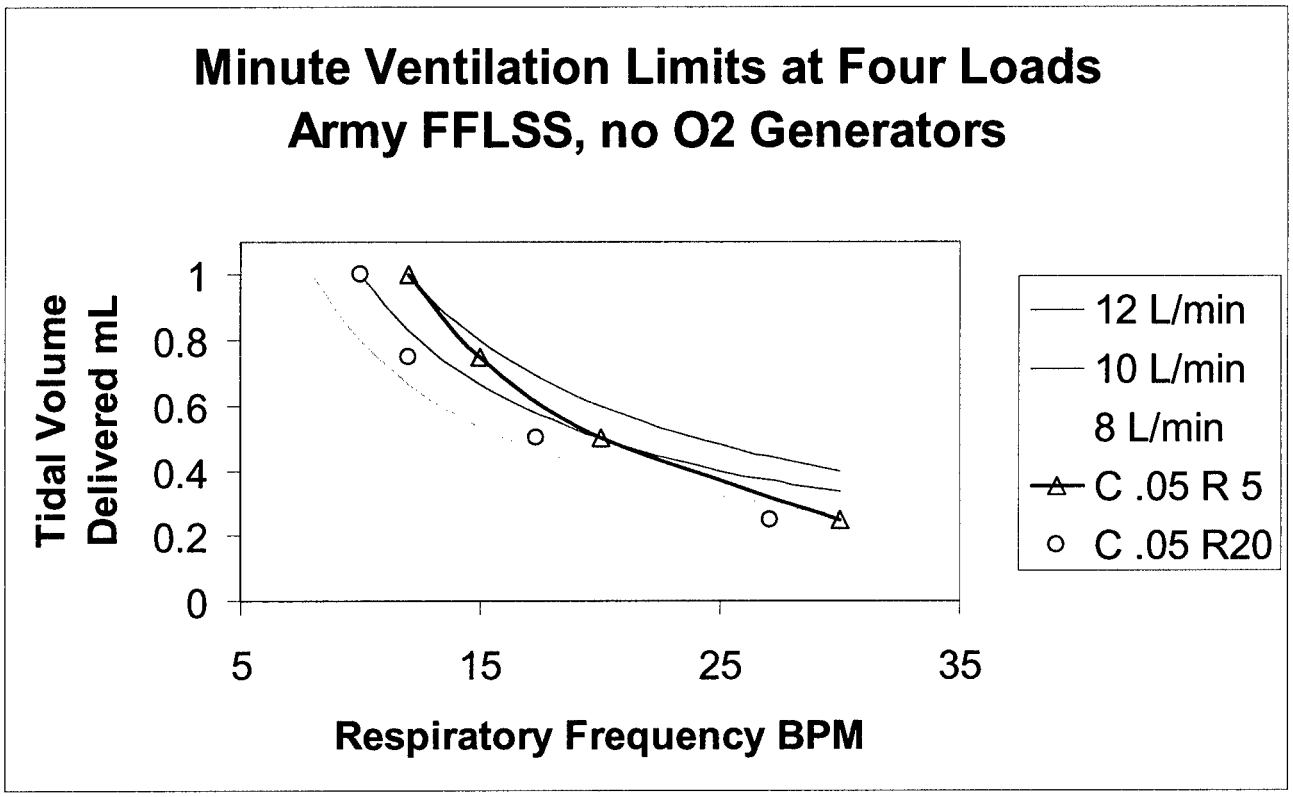

Figure 27 Final Prototype Performance

As seen in Figure 27, the performance for the prototype is quite acceptable but somewhat less due to a slightly increased inspiration time. The tradeoff was made to increase the ruggedness of the prototype and to incorporate a standard mechanical pop off valve in the ventilation circuit.

Note that ventilator inspiratory flow can be increased in three ways. First use the oxygen generators to increase the peak inspiratory flow by 4 - 6 lpm. Second, use any compressed air or oxygen source regulated down to 6 psi. Third, add another single or dual head compressor to the prototype. The battery will support another compressor and the manifold has ports to add another single or dual head compressor.

8.6 FFLSS Specifications

Dimensions 18.7 in x 12.8 in x 6.1
Weight 18.2 lbs without battery
Battery life 9.5 hours (BA-5590/U)
Fixed mechanical pressure relief set at 106 cmH2O

9 FDA TECHNICAL SPECIFICATIONS (REFERENCE ONLY)

Frequency (BPM)
Tidal Volume (Ml)
Minute Volume (L)
Inspiratory Time (Set)
Expiratory Time (S-X)
I:E Ratio:
Maximum/Peak Inspiratory Flow (Vmin)
Inspiratoly Peak Pressure Limit (Cm H_2O)
Inspiratory Pause/Plateau Time (Set)
Expiratory Resistance Pressure (Cm H_2O)
Expiratory Pause/Plateau Time (Set)
Spontaneous Ventilation Inlet Valve Pressure (Cm H_2O)
Oxygen Concentration Range (%)
Oxygen Concentration Accuracy
Sigh Frequency (BPM)
Sigh Pressure (Cm H_2O)
Sigh Volume (I&)
Inspiratory Relief Valve Pressure (Cm H_2O)
Minimum And Maximum Safety Pressure (Cm H_2O)
Minimum And Maximum Working Pressure (Cm H_2O)
Internal Compliance (L/Cm H_20)
System Input Pressure Control (Psig)
CPAP/PEEP Pressure Range (Cm H_20)
Intermittent Mandatory Ventilation (IMV) Frequency (BPM)
IMV Waiting Time (Set)
Inspiratory Trigger Response Time For Each Relevant Mode Of Ventilation
Inspiratory Bigger Pressure For Each Relevant Mode Of Ventilation (Cm H_20)
Inspiratory Trigger Volume For Each Relevant Mode Of Ventilation
Inspiratory Trigger Flow For Each Relevant Mode Of Ventilation
Inspiratory Delay Time For Each Relevant Mode Of Ventilation (Xc)
Internal Safety Relief Valve Pressure (Cm H_2O)
Available Modes (This information should include the trigger, control, limits, and cycle variables associated with each mode)
Available Waveforms
Flow Generator Type
Low Flow Generator Type
Fail Safe Mechanisms
Back Up Ventilation Parameters
Pressure Monitoring
Pressure Displays
Tidal Volume Monitoring
Tidal Volume Displays

10 NEXT STEPS FOR THE FFLSS

10.1 Doctrinal Foundation

Newly fielded medical material should support operational healthcare strategies. Joint Vision (JV) 2010 envisions the future battlefield as being more dispersed, with independent units responding to a flatter command structure. The lack of discernible front or rear lines will cause greater uncertainty and call for smaller units, often without medical support. Joint Health Services Support Vision (JHSS) 2010, the strategic foundation for the military medical community, changes the old concept of providing definitive care in theater and transporting stable patients to a new concept of essential care in theater, enhanced evacuation of stabilized patients, and definitive care out of theater. Joint Medical Logistics (JML) 2010 defines future medical supply based on the specificity of what goes to war, joint standardized equipment, and total asset visibility. The Joint Readiness Clinical Advisory Board (JRCAB) is tasked with the joint selection and standardization of medical materiel for in theater care during the initial two months of armed conflict. JRCAB maintains a verified, validated jointly approved list of medical materiel/equipment to take to war. Consequently, in-theater medical equipment now provides patient-driven essential care and is characteristically smaller, lighter, faster, and modular/flexible.

Previous medical policy treated patients in-theater for return to the battlefield. Depending on the theater and casualty rate, this approach often permitted definitive care and recovery. The current philosophy is less in-theater and more to stabilize and evacuate the patients. Consequently, FFLSS would have a greater role: patients would need it for transport from the rear (battlefield) hospitals to the out-of-theater hospitals for more definitive care.

10.2 Operational Concept.

Patient movement and evacuation may now occur earlier and more frequently than under previous health care concepts. Air Force evacuation of stabilized patients may occur in forward areas. The in-theater emphasis on essential care and movement of stabilized patients out-of-theater requires greater thought when selecting Patient Items (PTI) that may necessitate joint selection through the JRCAB process. In past conflicts, Army medical units direct exchanged PTI as the patient moved through the evacuation process, e.g., a patient remained on the same litter as he was evacuated with a one-for-one exchange of a litter passing between dismounted medic to field ambulance to MedEvac helicopter. Similar exchanges may now occur with more sophisticated PTI, such as the FFLSS. Service lines would be crossed quickly when MedEvac take Army patients to Air Force or Naval hospitals, or directly to fixed wing evacuation aircraft destined for out-of-theater. Patients supported on FFLSS ventilators would not be disturbed for property exchanges but would stay connected to the original FFLSS with like items being exchanged. This PTI concept is in keeping with the doctrinal requirements enumerated above. Adopting a portable ventilator for use as a PTI may need a variety of flexible features to satisfy multiple service users. Add-on features such as blood pressure monitoring, pulse oxymetry, IV warming, suction, multiple power source converters, etc. may be required to satisfy multi-Service users. A versatile FFLSS could eliminate need for maintaining multiple line items of PTI and could facilitate direct exchanges with minimal disturbance to the patient.

10.3 Certification

In addition to obtaining the usual FDA certifications of the device, dual airworthiness certification must be obtained for both rotary and fixed wing aircraft. Electromagnetic Interference/Radiated Magnetic Interference (EMI/RMI) certification is normally part of the foregoing processes. The JRCAB can assist in adding the FFLSS to the joint list so that it can be added to the joint core assemblages that enable commonality, compatibility, and interchangeability across the services.

11 SIMILAR VENTILATORS

The FFLSS was designed to meet specific requirements. As the system was finalized, we searched patents and commercially available systems to ensure no obvious features or shortcomings were overlooked.

The commercially available ventilators described below are examples of similar systems. None seems to have on-board physiologic sensors.

1. SIMS pneuPAC Ltd., Luton. U.K. --ComPAC 200
   A portable unit that can be driven with an internal compressor or external gas supply using battery, fixed power, or compressed gas. Developed in partnership with military and emergency organizations.

2. event Medical, Carlsbad, CA --Inspiration Ventilator System
   A bedside unit that uses external air with internal battery and compressor backup with intra-hospital capability.

3. Impact Instrumentation, West Caldwell, N.J. --Uni-Vent Model 754
   Company literature says compressor, but seems to be a portable, fan-powered ventilator that can also be run on external air. A review sent by the manufacturer indicates non-uniform flow from the fan and recommends using it (the fan) on an emergency basis.

The patent searches revealed some interesting ventilators (all without on-board physiologic sensors).

1. Pulmonetics, 28 Nov 2000 6,152,135
   This ventilator uses a drag compressor operating continuously. A complicated valve re-circulates the wasted air during exhalation and is used to measure flow. They also mention inlet and outlet silencer/accumulators, but not their size.

2. Bird Products, 16 March 1999 5,881,722
   This ventilator cycles the drag compressor on and off, but dumps the waste air during exhalation. It cannot vary flow during inspiration.

12 KEY RESEARCH ACCOMPLISHMENTS

- Ventilator is housed in form/fit/function packaging weighing less than 20 pounds
- Operation in excess of nine hours on one BA-5590/U battery

13 REPORTABLE OUTCOMES

Far Forward Life Support Prototype, SPIE April, 2001, Orlando, FL

"Low Pressure Valve" US Patent Application No. 09/681,249; filed March 6, 2001.

"Emergency Life Support System" US Patent Application No. 09/401,700; PCT Application No. 99/21241; both filed September 23, 1999.

14 CONCLUSIONS

This project successfully designed and fabricated a high-fidelity proof of concept FFLSS prototype that integrated a ventilator, microprocessor controller, three state of the art COTS physiologic sensors in a molded, rugged package. It was independently tested for performance and operated for more than nine hours on a single 12VDC battery.

15 REFERENCES

Draft Reviewer Guidance for Ventilators, July 1995, Anesthesiology, Respiratory, and Defibrillator Devices Group, Division of Cardiovascular, Respiratory, and Neurological Devices, U.S. Department of Health and Human Services, FDA.

ASTM F 1100-90 Standard Specification for Ventilators Intended for Critical Care.

General Principles of Software Validation, Draft Guidance, Version 1.1, U.S. Department of Health and Human Services, FDA, Center for Devices and Radiological Health, 1 June 1997.

Guidance for FDA Reviewers and Industry, Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices, U.S. Department of Health and Human Services, FDA, Office of Device Regulation

BS EN 794-1:1997	Lung ventilator
BS EN 475: 1995	Medical devices -Electrically generated alarm signals
ASTM F 1463-93	Standard Specification for Alarm Signals in Medical Equipment Used In Anesthesia and Respiratory Care
ISO 9703-1&2	Anesthesia and respiratory care alarm signals

ECRI. Intensive Care Ventilator [evaluation]. *Health Devices* 1998 Sept-Oct;27(9-10)

ECRI Infant Ventilators [evaluation]. *Health Devices* 1986 Aug;15(8)
ECRI Portable Volume Ventilators [evaluation] *Health Devices* 1992 Aug;21(8)
ECRI Physiologic Monitoring Systems [evaluation] *Health Devices* 1999 Jan-Feb 28(1-2)
ECRI Pulse Oximeters [evaluation]. *Health Devices* 1989 Jun;18(6)
ECRI Carbon Dioxide Monitors [evaluation]. *Health Devices* 1986 Sept-Oct; 5(9-10)
ECRI Health Devices, Vol. 21, No. 8, August 1992, pp 257-258.
Principles and Practice of Mechanical Ventilation, Tobin, Martin, J., 1994, McGraw-Hill.

16 APPENDICES

16.1 Variable Flow Valve

A variable control valve may be necessary to modulate air-flow into the patient to control the flow versus time (or pressure versus time) waveform. Accurate control of the I:E ratio (inhalation time to exhalation time) is impossible without this variable valve.

A thorough search of commercially available valves revealed that none met FFLSS requirements. All were either too heavy, too power hungry or did not allow sufficient flows at the low pressures in this system. The FFLSS operates at 1 psi maximum and less than 0.5 psi typical pressure. Nearly all commercial valves are designed for 50-100 psi and, therefore, are heavy with small orifices that do not allow sufficient flow at these low pressures. Additionally, the air compressor used in the FFLSS behaved like a constant flow source over a fairly wide range of pressures: narrowing a single orifice resulted in nearly no change in flow.

The valve designed for the FFLSS shifts flow to one of two outputs so that total load seen by the compressor and thus flow output remains the same. One output connects to the patient and the other vents to the atmosphere.

The first prototype was made using rapid prototyping techniques. Unfortunately, the tolerances were too loose and this valve had leakage that was too large to tolerate. A second design was precision machined from aluminum and Delrin AF. The motor is a high-speed, high-torque model airplane servo. The wiper in this valve needs to rotate through almost 180 degrees with each breath. The original servo proved too slow to allow accurate flow control. Valve assembly was very critical. In particular, the wiper and orifice plate need to be within 0.001" of each other to prevent air leaks across the surface to the incorrect output. If the orifice plate and wiper touch, they can bind and lock the servo.

The valve is controlled by pulse width modulation. Two versions of processor control were utilized. In one, the processor had a built-in pulse generator and the second design applied a voltage from a digital to analog converter from the processor controlled a separate pulse generator circuit. In both cases, once the valve was set, no processor overhead was used to maintain its position. The graph of flow versus pulse width is shown below in Figure 27. It was not a goal of this valve design to obtain extreme linearity because the processor software measures flow separately and could compensate for non-linearity.

In summary, an accurately controllable, relatively lightweight, and very low power valve was designed to allow the FFLSS to accurately generate various flow versus time curves for ventilation.

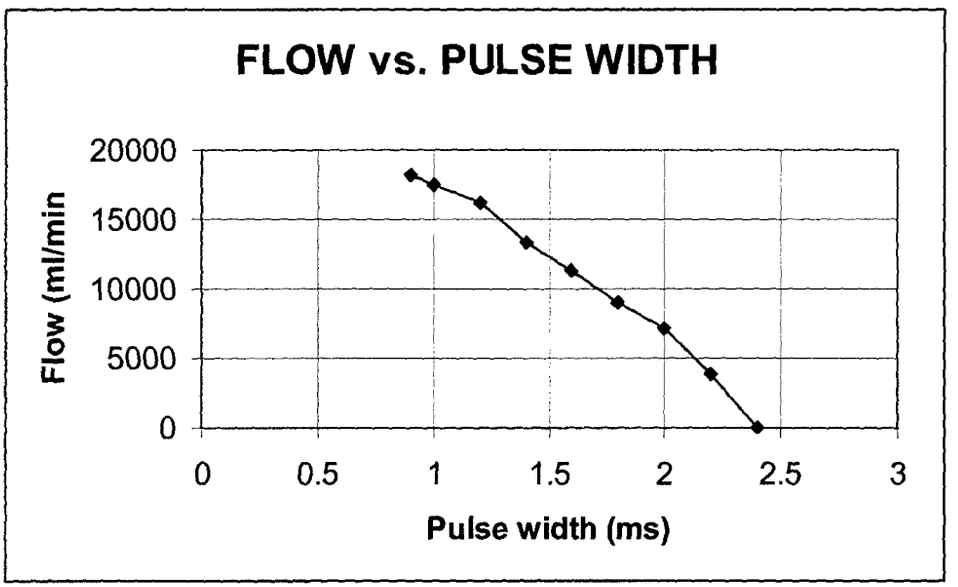

Figure 28 Proportional Valve Performance

16.2 Acronyms

10BaseT	Ethernet communications protocol for 10 Mega-bits per second through 4 twisted pair wires
AC	Alternating Current *also* a variable signal
A/D	Analog to Digital
BP	Blood Pressure
BPM	Breathes per minute
C4I	Command, Control, Communications, Computers, and Intelligence
CMV	Continuous Mandatory Ventilation
COTS	Commercial Off-the-Shelf
CPU	Central Processing Unit
DARPA	Defense Advanced Research Projects Agency
DEPMED	DEPloyable MEDical hospital
DC	Direct Current *also* the continuous offset value of a variable signal
ECG	Electro Cardiogram
EEPROM	Electrically erasable program read only memory
EKG	Electro Cardiogram (same as ECG)
EMI	Electro-Magnetic Interference
FAA	Federal Aviation Administration
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FFLSS	Far Forward Life Support System
FIFO	First-in, First-out
FPGA	Field Programmable Gate Array
GOR	Government Official Representative
HR	Heart Rate
I:E	Inspiratory to Expiratory Ratio
IEEE	Institute of Electrical and Electronic Engineers
IV	Intra-venous
JHSS	Joint Health Services Support
JHU/APL	Johns Hopkins University Applied Physics Laboratory
JML	Joint Medical Logistics
JRCAB	Joint Readiness Clinical Advisory Board
LCD	Liquid Crystal Display
LSTAT	Life Support for Trauma and Transport
NBC	Nuclear, Biologic, and Chemical
NIBP	Non-Invasive Blood Pressure
OEM	Original Equipment Manufacturer
PIP	Peak Inspiratory Pressure
PTI	Patient Items
RAM	Random access memory
RMI	Radiated Magnetic Interference
ROM	Read only memory

RS232	IEEE Recommended Standard # 232 for Computer Serial Communications
$EtCO_2$	End-Tidal Carbon Dioxide Levels (mmHg)
mmHg	millimeters of Mercury (measure of pressure)
SpO_2	Arterial Oxygen Saturation Levels (0-100%)
UART	Universal Asynchronous Receiver Transmitter
WRAMC	Walter Reed Army Medical Center

16.3 FFLSS Drawings

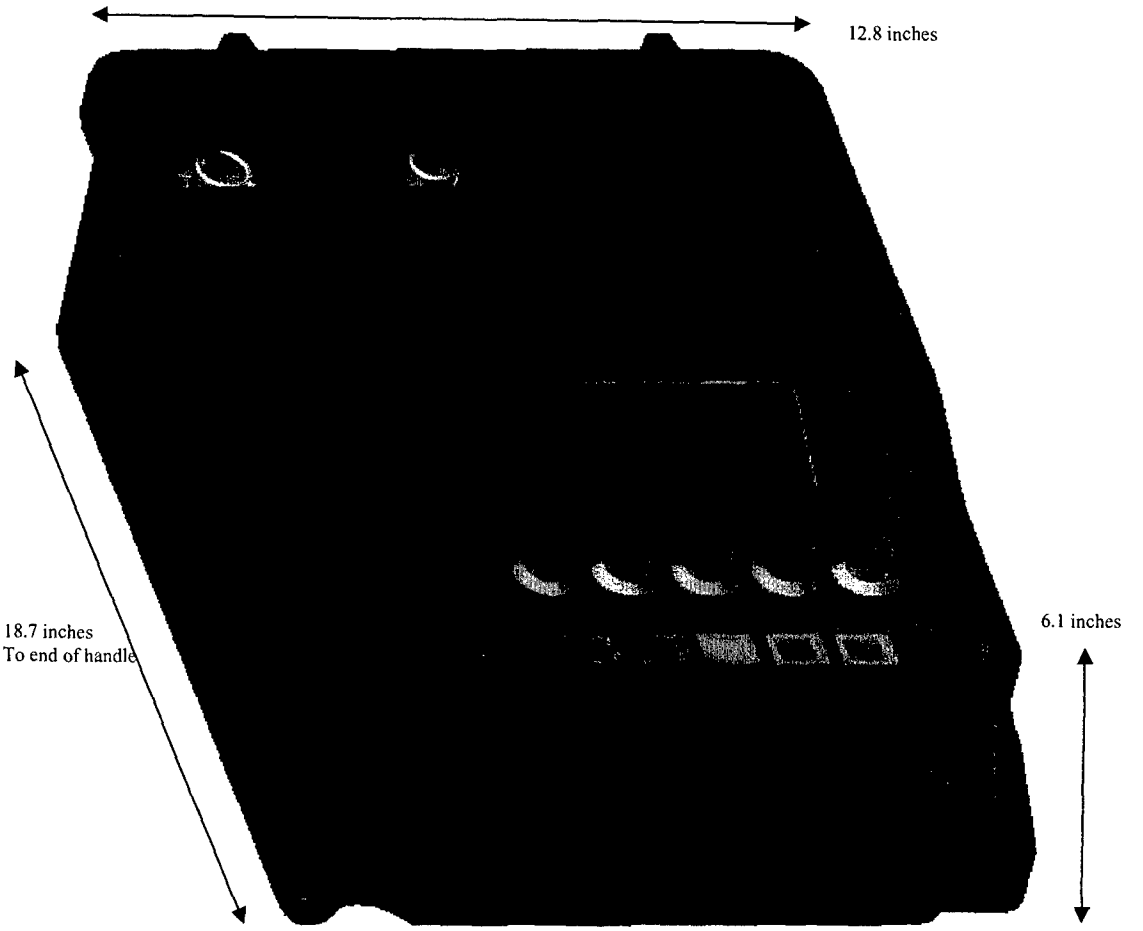

Figure 29 FFLSS Overall Dimensions

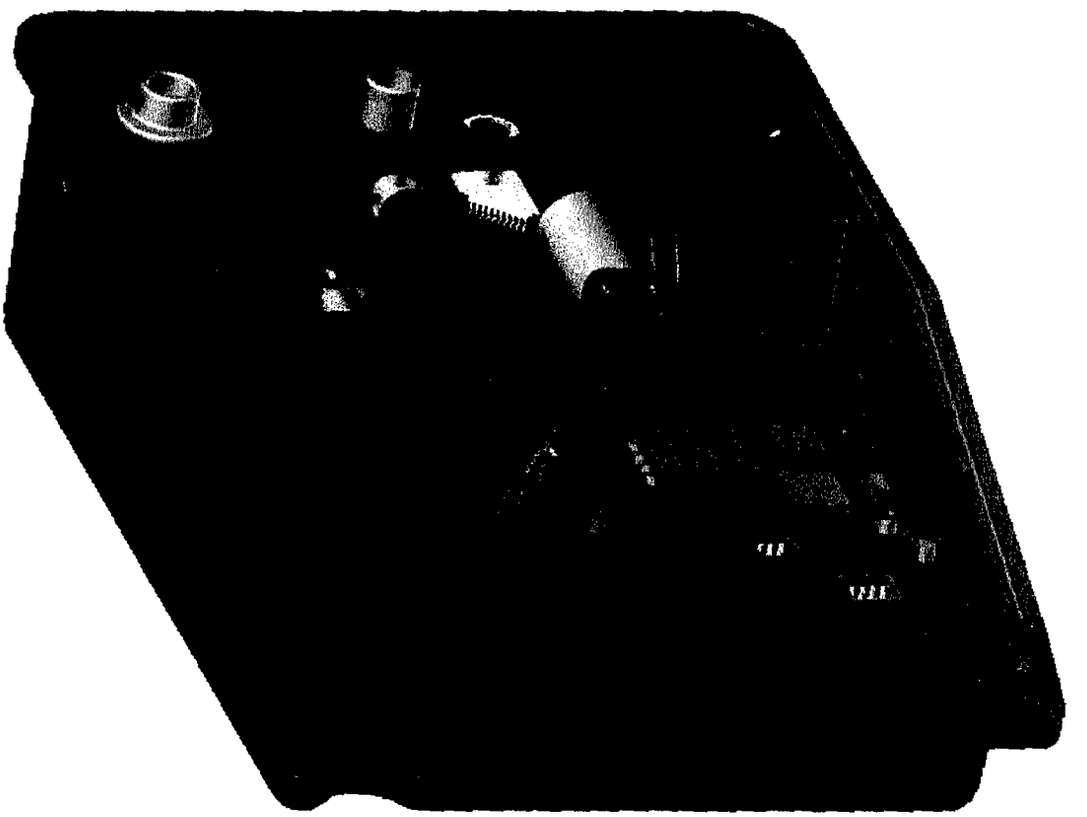

Figure 30 Interior View FFLSS

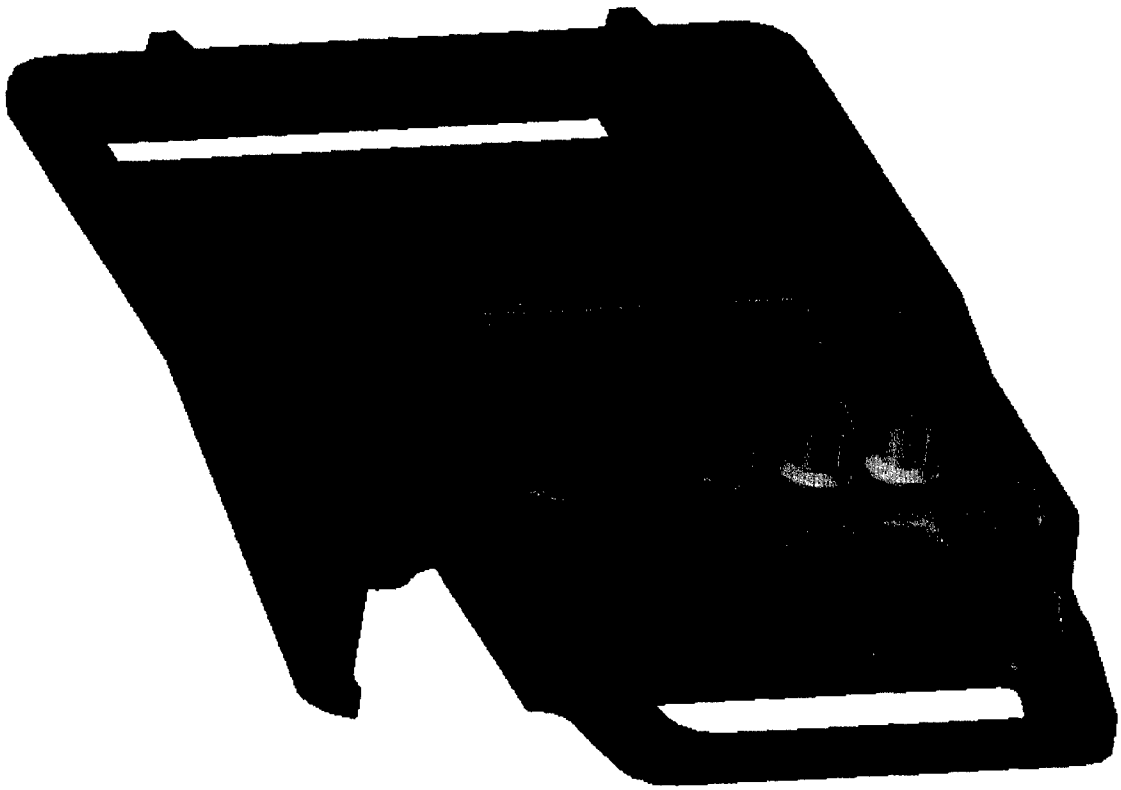

Figure 31 FFLSS Lid

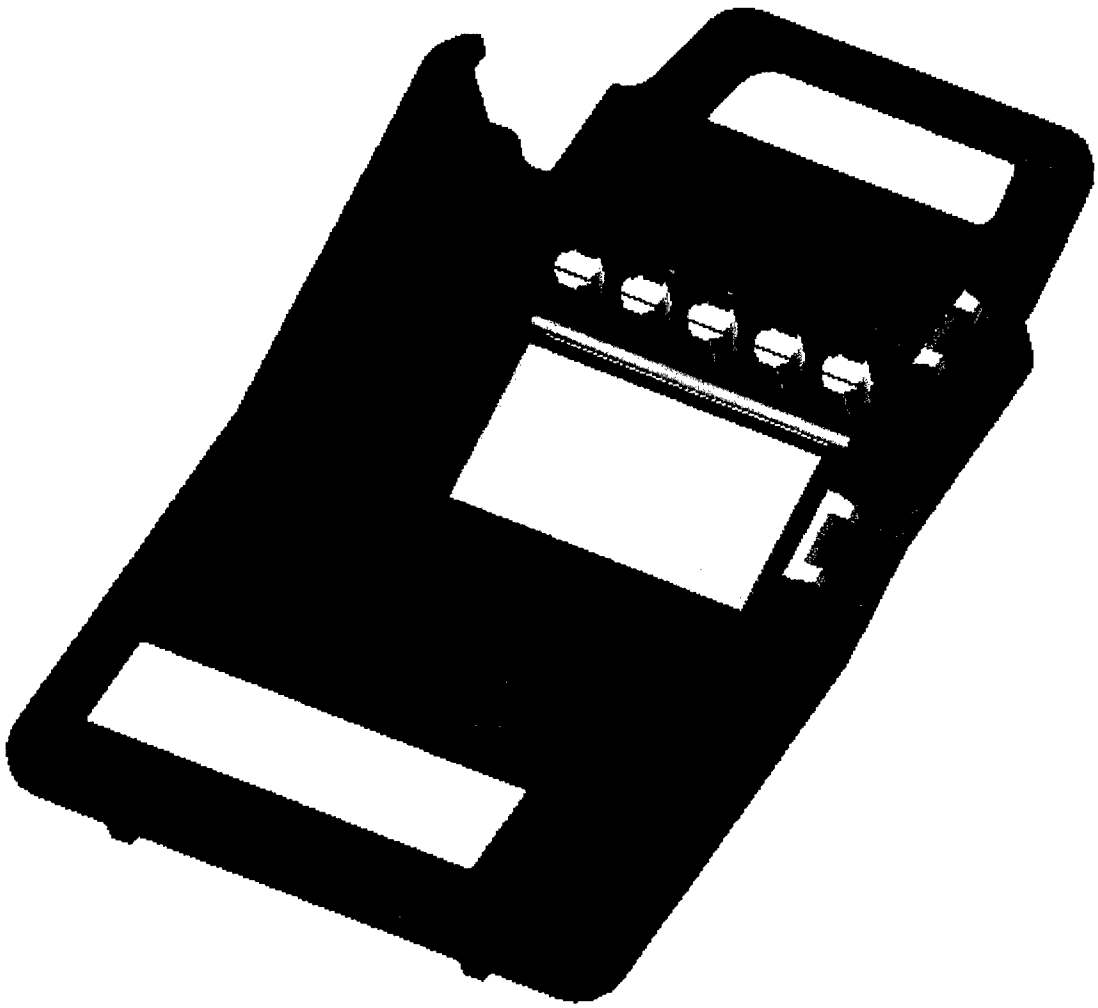

Figure 32 Underside of FFLSS Lid

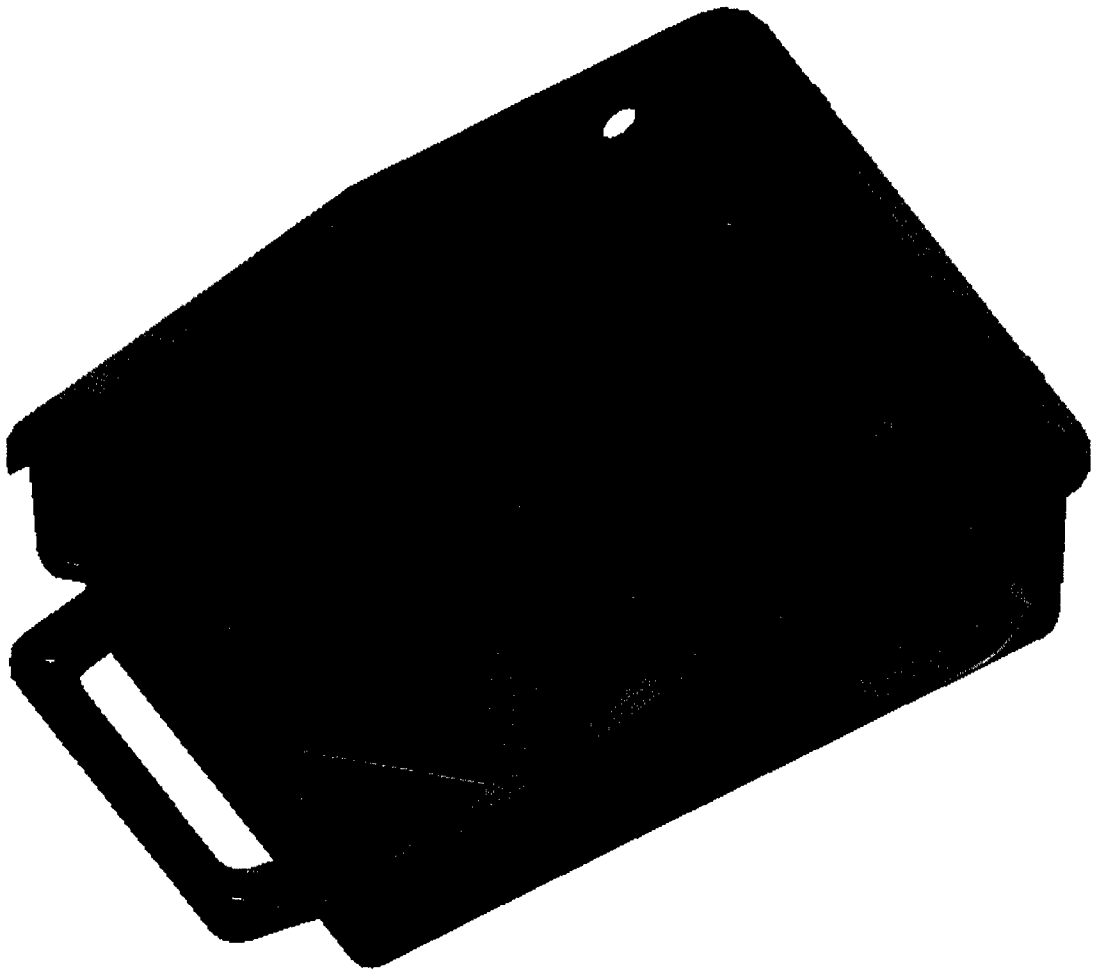

Figure 33 Unpopulated FFLSS Lower Case

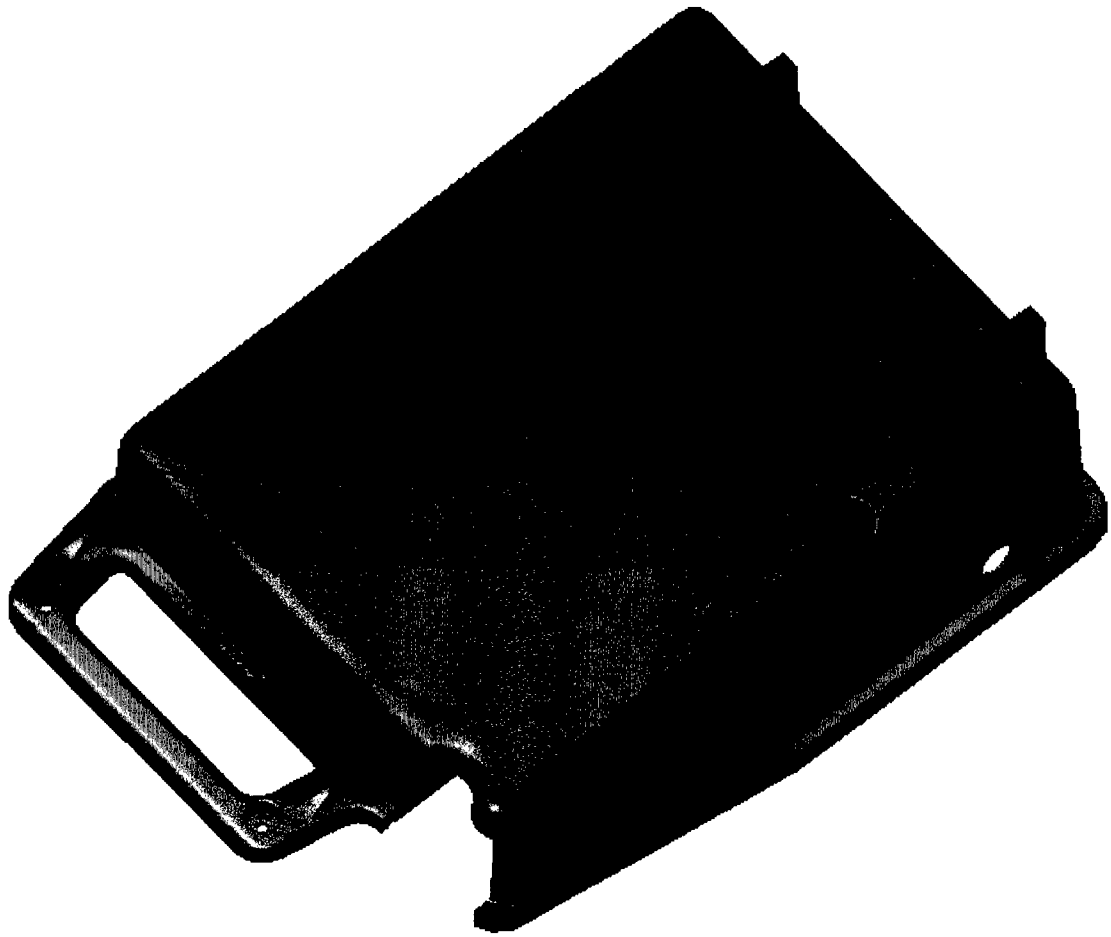

Figure 34 Underside of FFLSS

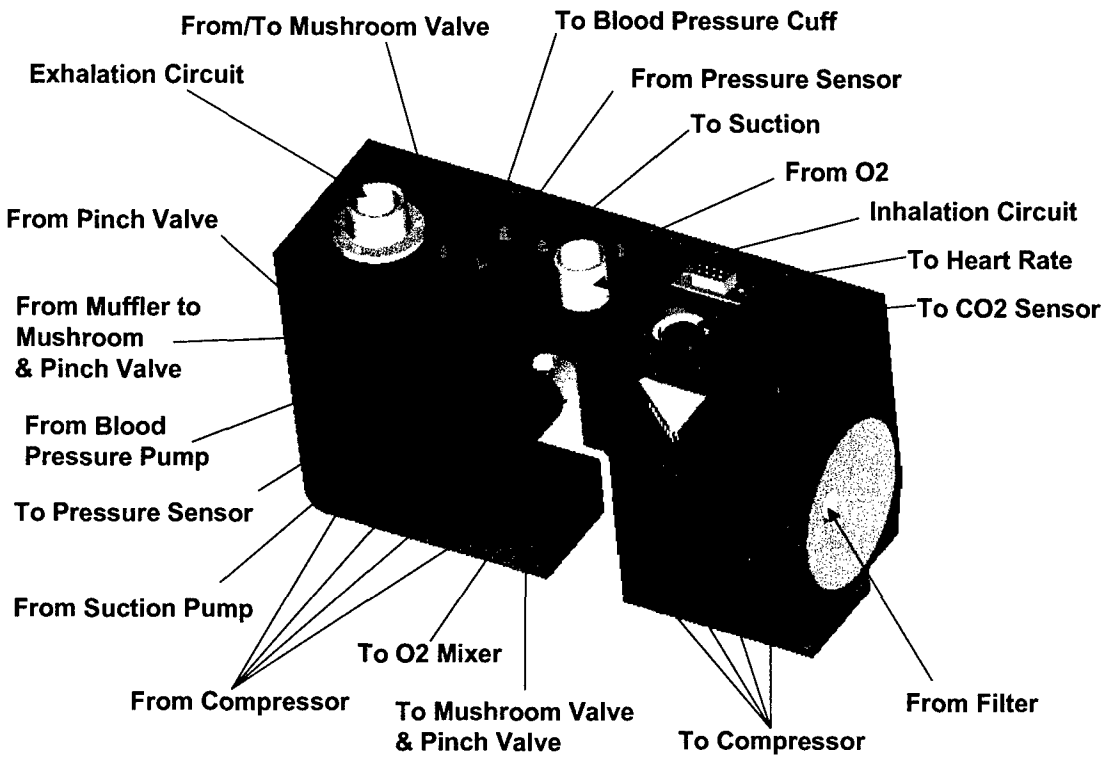

Figure 35 FFLSS Manifold Details

16.4 Version 1.0 Prototype Construction

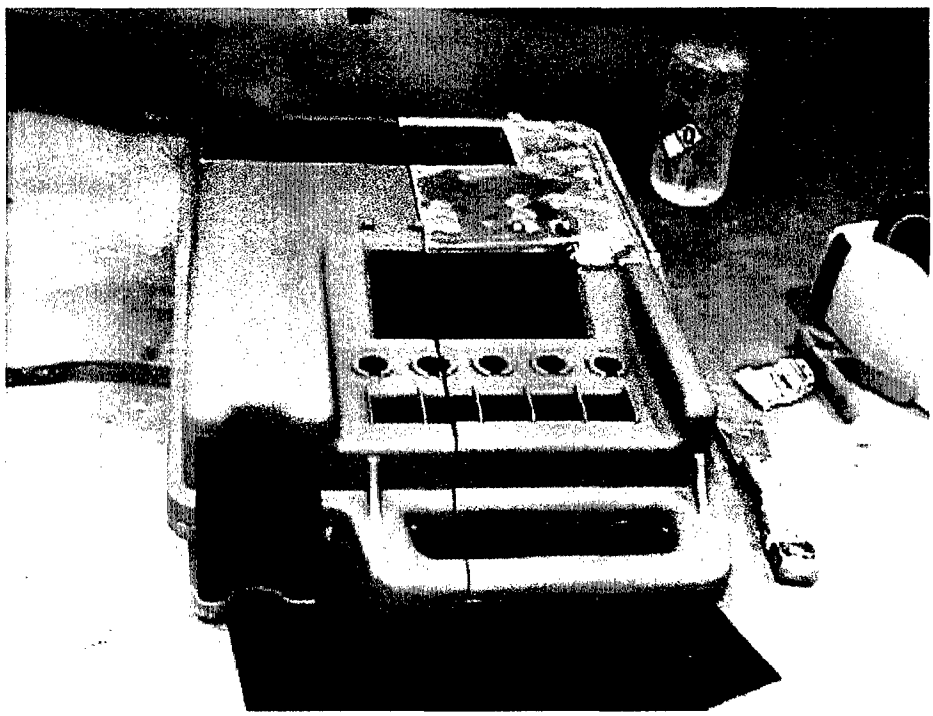

Figure 36 FFLSS Rapid Prototype Finishing Work

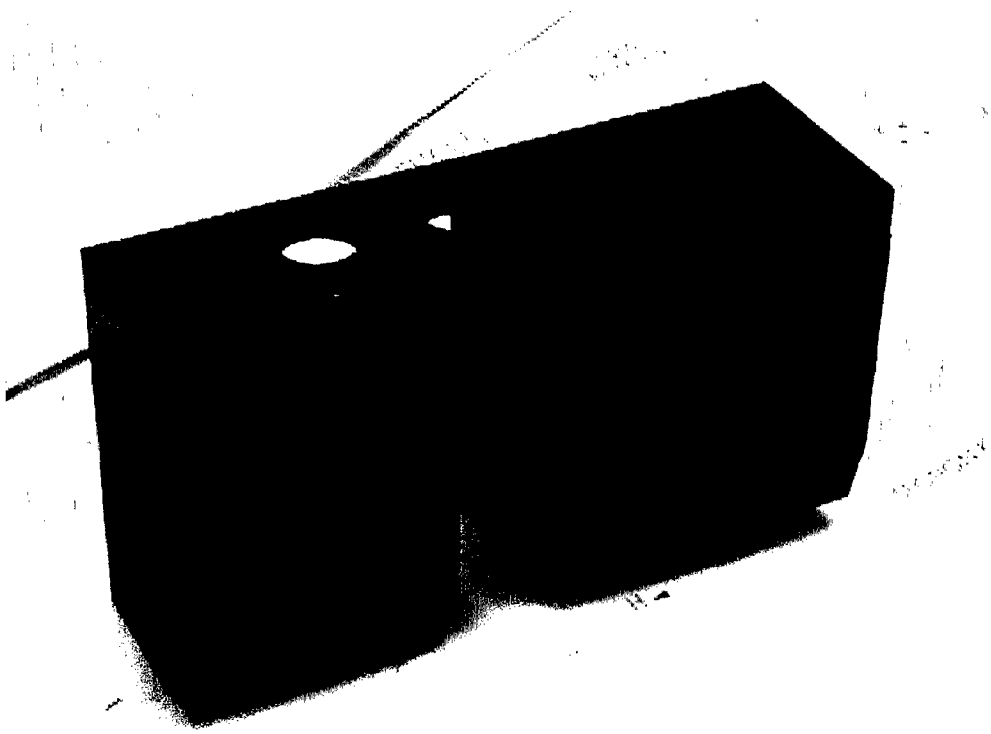

Figure 37 FFLSS Manifold

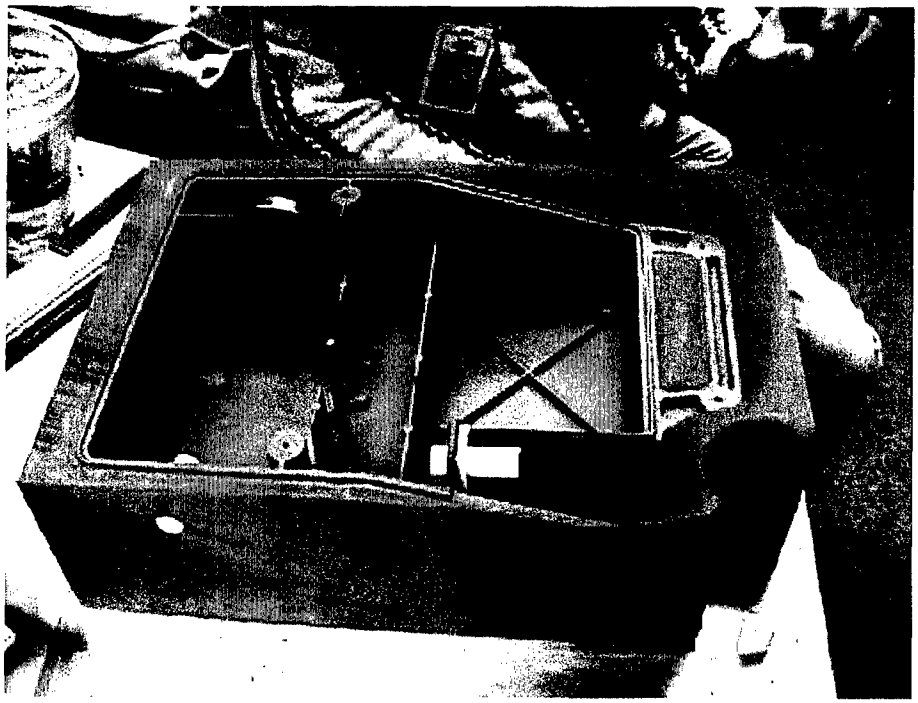

Figure 38 FFLSS Rapid Prototype Lower Case Mold

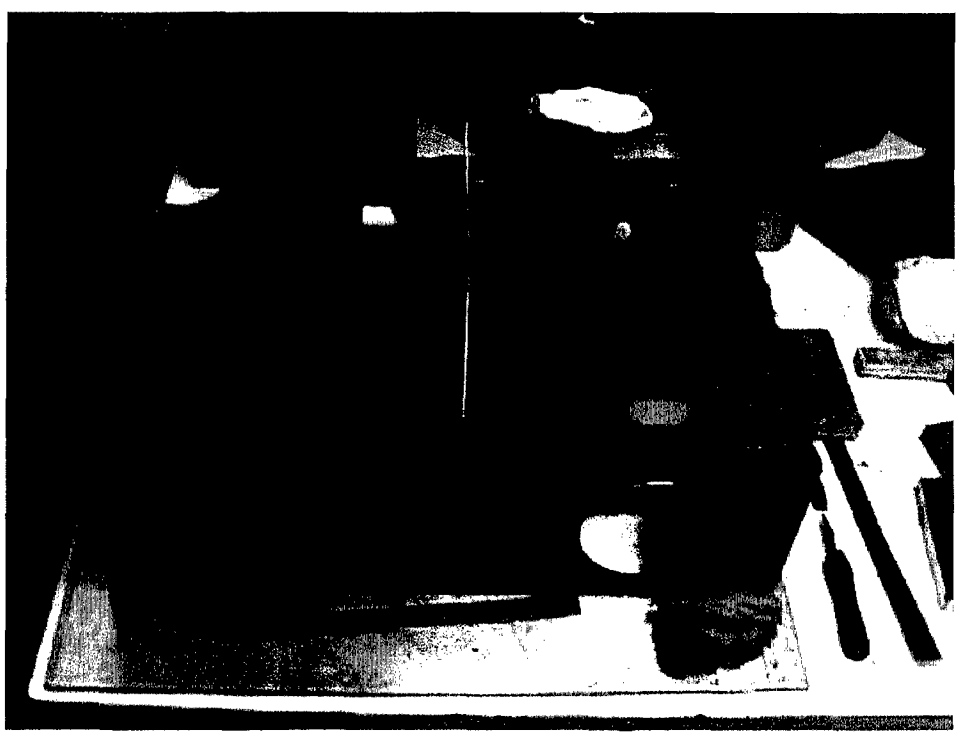

Figure 39 Both Pieces of Mold for FFLSS Lower Case

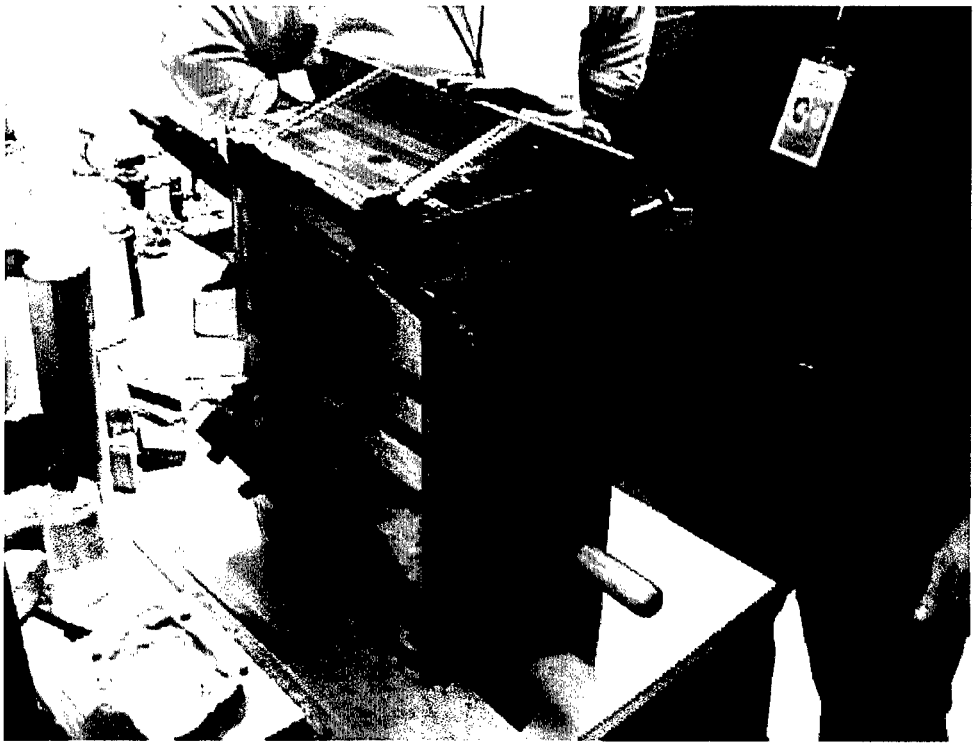

Figure 40 FFLSS Lower Case Mold in Rigid Form

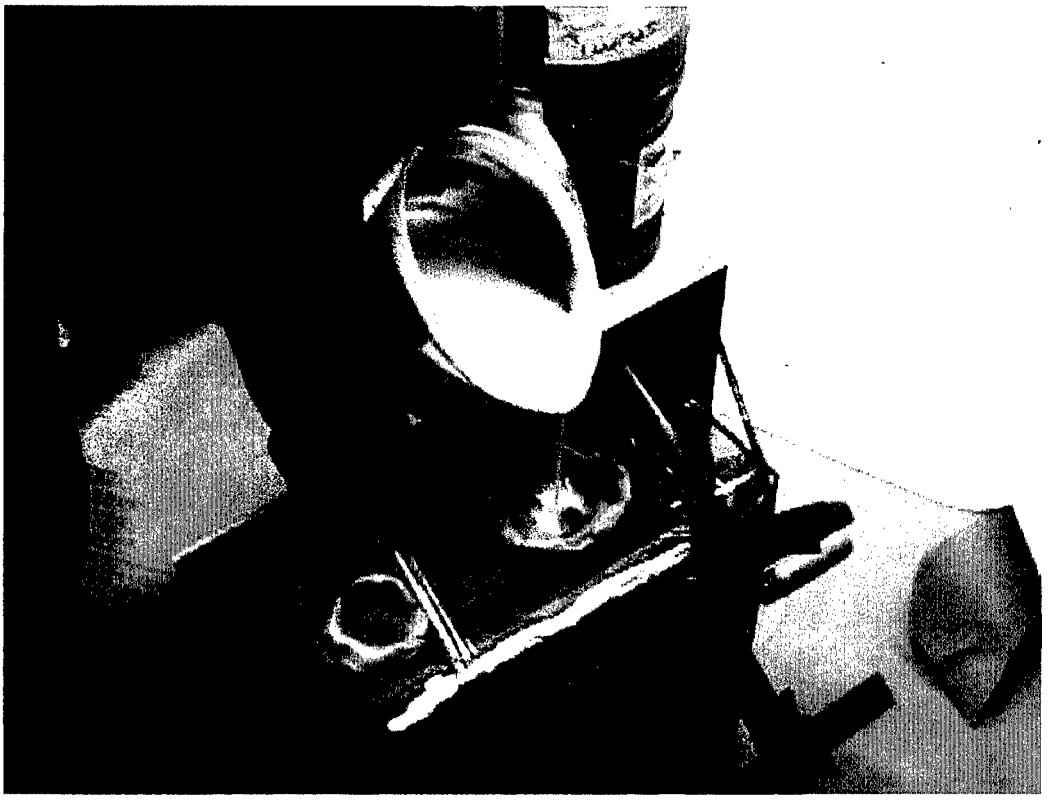

Figure 41 Pouring FFLSS Lower Case

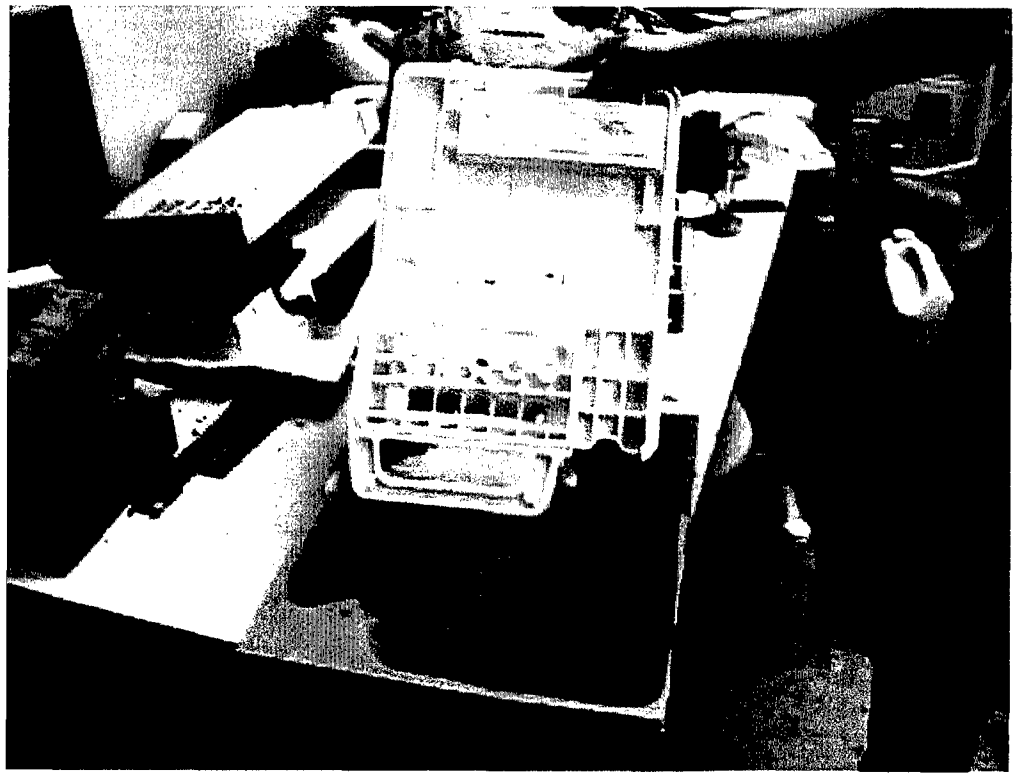

Figure 42 FFLSS Lid Just Out of the Mold

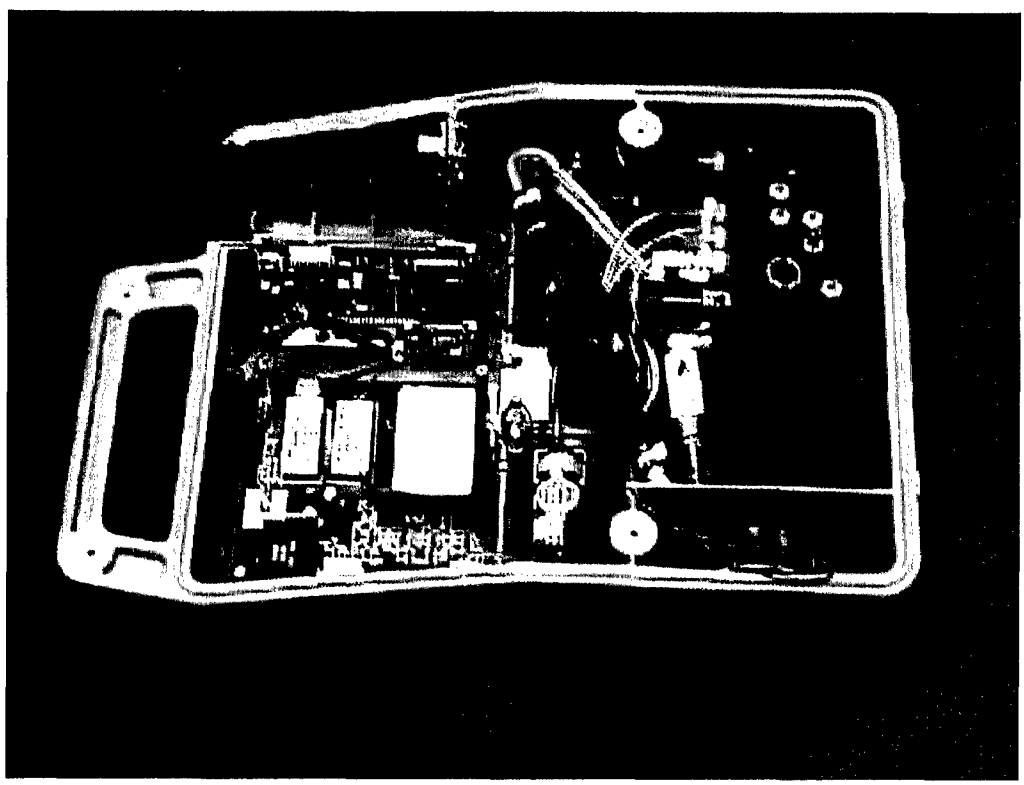

Figure 43 FFLSS Lower Case Being Populated

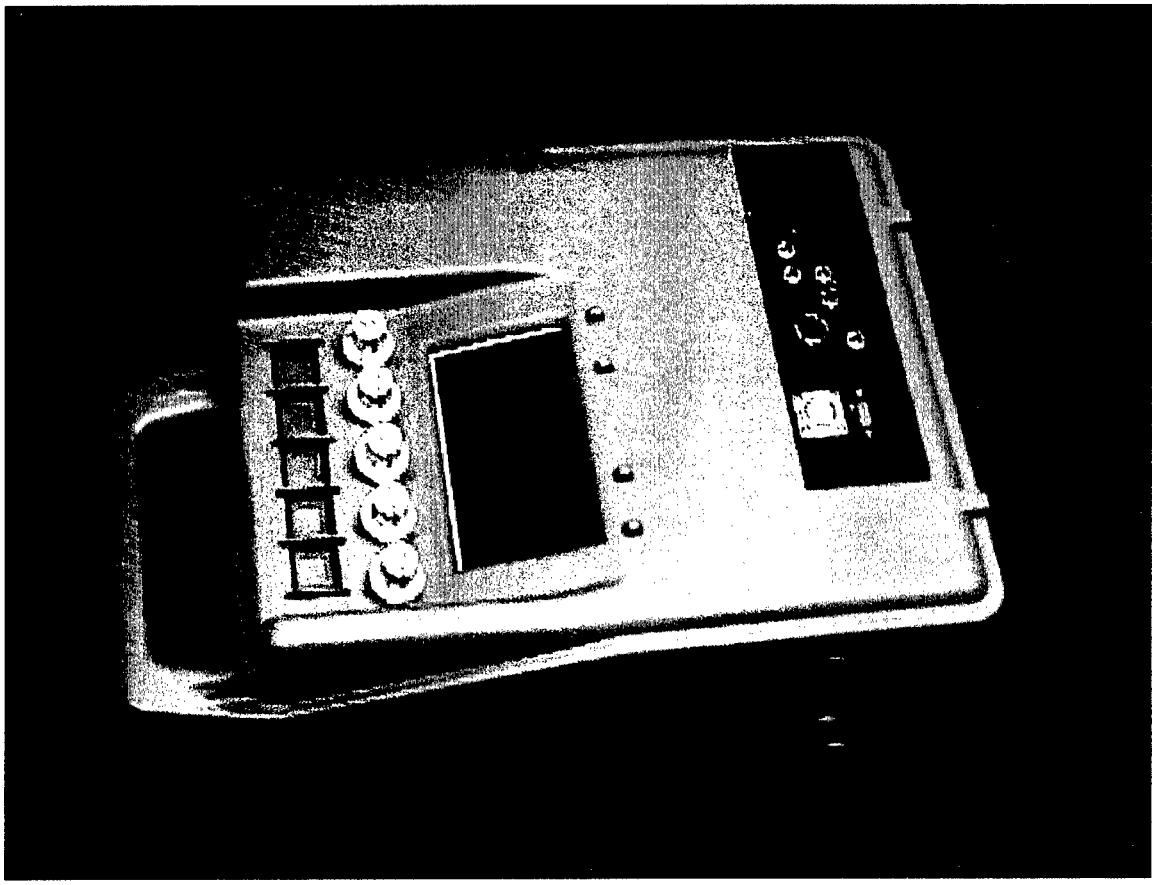

Figure 44 Completed FFLSS Version 1.0 Prototype

16.5 Parts List

Table 12 FFLSS Parts List

(highlighted items are kit bag components)

FFLSS Main Unit	# per sys	Kit Bag	Other
Sensor Systems			
Pulse Oximeter Sensor on bracket 1	1		
Capnography sensor on bracket 1	1		
Blood Pressure on bracket 2	1		
Fluid Resuscitation			
Infusion Pump (With the battery and pump)	1		
	1	IV fluids	
	1	IV infusion tubing	
Air Handling			
Air compressor	1		
Miniature Air compressor to control exhalation valve	1		
O2 and air mixer			
Mechanical Relief Valve	1		
Air Flow Sensor	1		
Suction Compressor	1		
	1	Suction Container	
Ventilator			
	2	Oxygen Generator	
	1		Oxygen Generator Mechanical Assembly
	1	Air Mask (Yellow)	
NBC Filter	1		
	1	Breathing Circuit	
	1	Laryngoscope Blade (w/ batteries)	
		Endotracheal Tube	
Processor Board			
CPU (mass is without chips)	1		
Pressure Sensor	1		
Power Supply Board			
Software			
User Interface			
LCD display	1		
LCD Switches with caps	5		
Knobs	5		
EM Noise filters	4		
Power Switch	1		
Suction Switch	1		
Alarm			
Base			
Lid			
Clear Cover			
Manifold			

16.6 Component Weights

Table 13 Component Weights

(highlighted items are kit bag components)

Component	# per sys	length (in)	width (in)	height (in)	Vol.per Sys (cu in)	Weight (g) each
Sensor Systems						
Pulse Oximeter Sensor	1	1.8	1.35	0.36	0.87	12.84
External Pulse Piece	1	1.5	1.25	1	1.88	30.73
Capnography sensor	1	5	3	2.5	37.50	1.25
External Cap. Piece	1	2.25	1.6	1.3	4.68	159.77
External Holding Clip						1.35
Blood Pressure	1	2.7	5	1.2	16.20	239.60
External Cuff	1	5.75	8	1	46.00	112.96
Fluid Resuscitation						
Infusion Pump (With the battery and pump)	1	4.25	2.75	2	23.38	263.94
IV fluids	1	4.5	10.5	2.5	118.13	1077.63
IV infusion tubing	1	2.75	2.5	0.5	3.44	8.45
IV fluid warming						
Syringe	1	1	1	6.5	6.50	25.18
Air Handling						
Air compressor	1	2	2.5	5.125	25.63	336.32
Miniature air compressor	1	2.6	1	1	2.60	131.60
Relief Valve	1					
Air Flow Sensor	1	6.4	1.4	1.27	11.38	60.30
Suction Source	1	3.25	1.5	2	9.75	218.70
Suction connector	1					
Suction Container	1	5.5	3.5	1.7	32.73	81.99
Ventilator						
Oxygen Generator	2	2.63	2.63	9.375	129.69	810.10
Oxygen Generator						799.59
Oxygen Generator Mechanical Assembly	1	8.5	4.5	12.5	478.13	1257.84
Screws For Assembly						20.75
Air Mixer	1					50.17
Air Mask (Yellow)	1	6.5	4	3	78.00	77.54
Esophageal Airway (Goes with yellow air mask)	1	13.5	0.5	0.5	3.38	38.94
NBC Filter	1	4.75	4.75	3.5	78.97	281.49
Breathing Circuit	1	14	14	3.75	735.00	373.36
Patient Pressure Tubing						69.61
Laryngoscope Blade (w/ batteries) (w/o batteries mass = 229.37)	1	8	1.75	1.25	17.50	369.86
Endotracheal Tube						22.10
Processor Board						
CPU (mass is without chips)	1	4	5	0.625	12.50	166.78
Pressure Sensor	1	1.04	0.63	0.22	0.14	included above
Pressure Sensor Connector	1					
Software						
User Interface						
Rate Optical Encoder	1	1	1	1	1.00	46.06
I:E Ratio Optical Encoder	1	1	1	1	1.00	46.06
Maximum Pressure Optical Encod	1	1	1	1	1.00	46.06
Tidal Volume Optical Encoder	1	1	1	1	1.00	46.06
Other Optical Encoder	1	1	1	1	1.00	46.06
LCD display	1	6.75	4	0.75	20.25	246.45
LCD Switches	5	1	1	1	5.00	90.72
Power Supply Board						388.40
Alarms						
Package						
Base						1974.90
Lid						1030.58
Clear Cover						208.84
Manifold						1257.58
Mountings & Attachments						
Power Supply						388.40
Main Battery (14.4 Ah)	1	2.7	2.7	2.5	18.23	1035.21

16.7 Component Powers

Table 14 FFLSS Device Powers

	Measured at Device (when possible)		Measured at Power Source	
Individual Component	**Device Supply Voltage (V)**	**Device Current Draw (A)**	**Battery Voltage (V)**	**Battery Current Draw (A)**
Sensor Systems				
Pulse Oximeter Sensor	5	0.01	12	0.023
Capnography Sensor				
(Before Heating)			12	0.439
(After Heated)			12	0.292
Blood Pressure				
(No Inflation)	12	0.03	12	0.047
(During Inflation)	12	0.22	12	0.333
Air Handling				
Air compressor			12	0.7
Miniature air compressor			12	0.04
Relief Valve				
Air Flow Sensor				
Air compressor, suction (700ma full load)			12	0.372
Processor Board				
CPU			12	0.48
Pressure Sensor				
User Interface				
5 Optical Encoders				
LCD display				
(No Backlight)				0.006
(With Backlight)				0.179
LCD Switches				0.051
Total				2.962

16.8 Manufacturers and Costs

Table 15 Key Component Manufacturers

Component	Manufacturer	Contact Info	Model #	P/N
Sensor Systems				
Pulse Oximeter Sensor	Nonin	2605 Fernbrook Lane North Plymouth MN 55447-4755 800-356-8874	OEM2	2332-001
External Pulse Piece	Nonin			
Capnography sensor	Novametrix Medical Systems	5 Technology Drive Wallingford, CT 06492-1926 800-243-3444	MICROCAP	58350A1
External Cap. Piece	Novametrix			
External Holding Clip	Novametrix			
Blood Pressure	CAS Medical Systems	44 East Industrial RoadBranford, CT 06405 800-227-4414	NB Module	
Fluid Resuscitation				
Infusion Pump (With the battery and pump)	Infusion Dynamics	5209 Militia Hill Rd Plymouth Meeting, PA 19462 610-941-0136	DBP M100	0040-0030
Air Handling				
Air compressor	Sensidyne Micro-Air Pumps	16333 Bay Vista Dr. Clearwater, FL 33760 800-451-9444	C pump DH 12 V Press	CD120INNNF60PC4
Suction compressor	Sensidyne Micro-Air Pumps		C pump CW 12V Micro Air-Vacuum	CD120INSNF50VC1
Miniature Air Compressor	Fluid Power, Inc.	10451 Mill Run Circle, Suite 400, Owings Mills, MD 21117 410-646-1545	G02	G12/02-8
Relief Valve	Smart Valves	Smart Products, Inc. 1701 Ringwood Ave, San Jose, CA 95131 800 338 0404	304PPB - 1.5, psi 8 gallon / minute Note: 1.5 psi = 106 cmH2O	
Air Flow Sensor	Honeywell	PO Box 4000 Morristown, NJ 07962 973-455-2000	AWM5104VN	
Ventilator				
Oxygen Generator (2)	Scott Aviation	Lancaster, NY 14086 716-683-5100		802093-01
Oxygen Generator AVIOX 2	Scott Aviation			
Air Mixer	Scott Aviation			
NBC Filter	3M	Occupational Health & Envrionmental Safety Division PO Box 33275 Saint Paul, MN 55133 800-243-4630	C2A1 NBC	460-01-06
Breathing Circuit	Allegiance Healthcare	1430 Waukegan Road McGaw Park, IL 60085 800-964-5227	Cat. 003764 Universal Portable Volume Ventilator Circuit	
Main Battery (14.4 Ah)	Fedco	FEDCO Electronics, 1363 Capital Drive, Fond Du Lac, WI 54937 920 922 6490	BA-5590/U	

16.9 ECRI Recommendations for Alarm Strategies

This section describes the basic criteria for the FFLSS alarms that are currently being designed at JHU/APL. These criteria are based upon ECRI's 25 years of experience evaluating medical equipment, and our understanding of the design and the intended use of the FFLSS. The typical patient for this device will be an injured, but otherwise healthy young adult.

16.9.1 Alarm Characteristics For Entire Life Support System

- Both an audible and visual indication should be present for any alarm condition that poses a significant risk to the patient -as battlefield conditions will allow. Visible: perhaps flashing the button colors?
- If the battlefield conditions call for silencing audible alarms and dimming visual indicators, some alternative but comparable method of alerting the caregiver must be provided. We haven't really talked much about this (pager interface...etc.)

    — When referring to alarms and indicators, we are considering audible and visual indicators as well as some other means to indicate (e.g. vibration) that an alarm has occurred which might be used to take into account battlefield conditions. To emphasize this we used italicized *alarm*.

- Audible *alarms* should sound as long as the *alarm* condition is present or until the *alarm* is acknowledged by a caregiver (e.g. silenced).
- *Alarm* limits should be, preferably, continuously displayed along with the monitored value.

I'm not really sure that we can continuously display all the alarm limits and values at the same time. Lots of different alarms are desired, and they will probably not all fit on the screen. Certainly though, we can have an alarm threshold set screen which can display the currently monitored values as well. The main problem is that the graph takes up a lot of the room on the display, maybe we should be able to turn that on and off.

Initialization

- The *alarms* should be functional as soon as the unit is turned on.

Alarm Prioritization

- *Alarms* for immediately life-threatening events should be clearly differentiated from other noncritical *alarms* and indicators (e.g. power failure, low battery, and communications failure should be continuously sounding and nonsilenceable *alarms.*)
- Higher-priority (i.e., more critical) audible *alarms* should override lower-priority ones.
- An audible or other notice should be provided to signal a new *alarm*, even if another *alarm* is sounding.

Identification

- The cause of each *alarm* condition should be readily identifiable by the user by text display or other means.
- Visual indicators (e.g. alarm-defeat and alarm-silence indicators, alarm messages, and alarm identifiers) should be easy to see and identify at distances of at least 3 ft and at viewing angles of at least ±60° from perpendicular to the plane of the display at all light levels anticipated in use environments.

The button backlights can be flashed with differing colors.

Alarm Volume

The *alarm* volume should be adjustable.

- *Alarm* volumes should be sufficiently loud and/or distinctive (e.g., intermittent or varying tones) to be heard over noise commonly occurring in areas where the unit is used. When an audible *alarm* mode is in use, *alarms* should provide an adequate warning that can be heard and recognized by caregiver, even at their lowest volume settings.
- *Alarms* should not be extremely loud, abrupt, or annoying because such *alarms* can cause startle reactions or interfere with staff communication and response or may encourage the staff to defeat or silence the alarms.

The computer does not have much control over the audible buzzer circuit. All it does is buzz if the computer stops hitting the watchdog inputs.

A second remote piezo beeper was added.

Nuisance Alarms

- Mechanisms should exist to minimize nuisance *alarms*; such mechanisms should include the following:
  - A silence function that disables sounding audible *alarms* for a prescribed time, preferably within 120 sec; the silence mechanism should be activated by a single action (e.g., one keystroke).
  - An *alarm* standby mode, in which *alarms* can be disabled but will subsequently be automatically enabled when the monitor recognizes that a patient is connected to the system.

Disabling and Silencing

- If the *alarm* is defeated or silenced, this condition should be identified by a prominent, continuously displayed (either constant or flashing) visual indicator whose meaning is unambiguous.
- A new alarm will override the disabling.
- *Alarms* should be automatically reactivate within a reasonable time (e.g., 2 min) to prevent *alarm* conditions from being undetected or ignored.

Alarm Limits

- Adjustable *alarm* limits should be easy to set and view. To ensure that the *alarms* are properly set, the limits should be continuously displayed along with the value of the monitored variable or easily accessible via an embedded screen.
- Default settings—or, alternatively, a method of automatically setting all *alarm* limits to settings appropriate for the patient—should be accessible for a new patient set up.

Remote Alarm

Because battlefield conditions may be such that the caregiver may not be in close proximity to the unit, the unit should be equipped with a remote alarm system.

- The remote *alarm* device or system should reliably convey all alarms.
- If multiple units will be monitored with a remote device, the indicator should identify which unit is alarming.
- Remote *alarms* must provide an audible fault indicator for (1) communications failure (2) a ventilator low-battery condition (3) loss of remote alarm power.
- A TEST switch or an easy test method should be present for immediately verifying remote alarm operation.

Inaudible Mode

- Activating the inaudible mode should require a 2 step procedure.
- Some type of clear indication (e.g. vibration) must be provided to indicate an *alarm* has occurred.
- There should be a constant visual display on the unit and remote alarm indicating the unit is in the inaudible mode.

16.9.2 Ventilator Alarms and Safety Mechanisms

- The ventilator should *alarm* for events that are immediately life-threatening to the patient; such events include:
- No gas delivery or excessive gas delivery
- Exhalation valve failure in either the open or closed position
- Power or gas supply failure : If power goes, it may be hard to alarm for long. If just the 5V fails, the buzzer should buzz, but certainly nothing else will happen
- Ventilator deactivation
- *Alarms* for such events should be noncanceling and nonsilenceable for conditions that require replacing the ventilator (e.g., in the event of a ventilator malfunction).
- The ventilator should also *alarm* for events that are potentially life-threatening if left uncorrected; such events include:
- High Peak Inspiratory Pressure with setting at 8-10 cmH_2O above PIP We right now have the computer forcibly halt a breath if the pressure goes up to the max pressure dialed in on the knob. It sounds like this should just be an alarm, and we should continue to deliver the appropriate volume.

- Low and High Exhaled Minute Volume with the low and high limit set to within +/- 10% to 15% of the MV.
- Also, the unit should have an *alarm* for oxygen cell depletion. - time only

16.9.3 Safety Mechanisms

- The ventilator should provide some protection against injury to the patient while the clinician responds to *alarms* and during general use. Specifically:
  — If the ventilator fails, it should not impede the patient from breathing spontaneously through the device. The FFLSS should be removed from the patient to allow manual bagging.
  — A ventilator should provide a user-adjustable pressure-relief mechanism that causes the ventilator to *alarm* and cycle to exhalation once the pressure limit is reached. Ventilators should be able to relieve excess pressure even if the exhalation valve is blocked.
  Our ventilator as is currently stands can do most of this, though the relieving of excess pressure if the tube is blocked can only happen via our overpressure mechanical relief valve.
- Mechanisms should exist to protect against inadvertent adjustment of settings.

16.9.4 Monitors

Pulse Oximeter

- Should have audible or other *alarms* for system failure, high and low spO2, high and low pulse rate and probe failure/ disconnection.
- The high spO2 *alarm* limit should be adjustable from at least 90% to 100% spO2 for the range of patients.
- The low spO2 *alarm* limit should have a default setting no lower than 80% and should be adjustable up to 95%, but no lower than 70% for the range of patients.
- The high and low pulse rate alarm *limit* range should be adjustable from 30-250 bpm for the range of patients.

NIBP

- Should have audible or other *alarms* for system failure, noisy signal, cuff not detected, wrong cuff.
- *Alarm* limit range:

	Systolic
High	70 - 240 mmHg Adult
	40 - 180 mmHg Ped
	30 - 130 mmHg Neo
Low	50 - 150 mmHg Adult
	25 - 130 mmHg Ped
	15 - 130 mmHg Neo

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